ASPIRE 2025

Submission on the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill

Key points

1. We strongly endorse the Bill's commitment to implement three key policy measures: (mandated denicotinisation, supply reduction, and the smokefree generation [SFG]). We believe the Bill may be the largest single legislated step ever proposed to improve health and health equity in Aotearoa.
2. We commend implementing the Bill's three key measures as part of a comprehensive strategy, alongside supporting measures outlined in the accompanying Smokefree Aotearoa 2025 Action Plan. We recommend that a detailed strategy for introducing the supporting measures is developed and implemented as soon as practicable
3. We note several aspects of the Bill that could be further strengthened to maximise the probability of rapidly reaching the Smokefree Aotearoa 2025 goal for all peoples in Aotearoa. These include the following:
    i. The timelines and sequencing of the Bill's key measures need to be reconsidered. Specifically, it is important that the introduction of denicotinised tobacco is expedited so that this measure is fully implemented before the retail restriction policies come into effect.
    ii. We are greatly concerned about the reliance on regulations to set out key details of the three main measures' implementation. Specifically, we recommend that the Bill (rather than post-enactment regulations) specifies the number of retail outlets that will be permitted and the maximum level of nicotine that will be allowed in smoked tobacco products (STPs).
    iii. We are concerned that the Bill does not adequately regulate heated tobacco products (HTPs). Given the wide availability of a broad range of vaping products, the likely greater harmfulness of HTPs compared to vaping, the lack of evidence that HTPs assist smoking cessation, and the uncertainty that HTPs will help reduce smoking prevalence, there is a strong public health rationale for including HTPs in the definition of STPs and treating HTPs as STPs for regulatory purposes.
4. We strongly support the commitment to honouring Te Tiriti o Waitangi made in the Bill and the Smokefree Aotearoa 2025 Action Plan's focus on eliminating inequities in smoking and smoking-related illness.
5. We recommend some changes in wording within the Bill including that the Bill should refer only to "Te Tiriti o Waitangi", that references to "principles" are amended to "principles and provisions", and that "consultation" with Māori should be replaced with "engagement" throughout the Bill.
6. We also recommend that references to Te Tiriti obligations and the requirement for Māori engagement should be included for all aspects of the Bill, particularly for the three key measures, and that the Bill formally establishes an independent Māori governance group to oversee its implementation.
7. We note that the purposes of the Bill have been amended with reference to vaping and the need to reduce youth uptake of vaping; we recommend that the purpose section be reviewed to clearly set out the Bill's over-arching aims and that the purpose of protecting youth from vaping is reinserted.

8. We strongly support the mandated denicotinisation of STPS; we believe it is the single most important intervention included in the Bill and is likely to result in rapid and profound reductions in smoking prevalence.
9. We recommend that the Bill is strengthened by specifying: (i) the maximum level of nicotine (≤0.4mg /g tobacco) in the Bill itself, (ii) an immediate rather than gradual reduction in nicotine content and (iii) that testing of nicotine levels of STPs should be undertaken by an independent, agency at the manufacturers' or importers' expense, with a timeframe for establishing the testing system stated.
10. We strongly support the policy measures to reduce the number of tobacco retailers, sequenced to occur after denicotinisation, with a date specified for completion. We recommend the Bill sets a **maximum number** of STRs (<300) to greatly reduce the retail availability of STPs and density of tobacco retail outlets.
11. We strongly support introducing criteria that retailers must satisfy before they can become a permitted STR. We suggest the Bill specifies a time period for permits (2 years) and criteria for permit renewal.
12. We strongly recommend that no internet sales of STPs are permitted to prevent manipulation of this sales platform undermining measures restricting STR numbers.
13. We strongly support the introduction of the SFG policy as a proportionate response to managing a highly dangerous and addictive product. This measure will sustain reductions in smoking prevalence by minimising future smoking uptake.
14. We welcome that the SFG applies to the sale or supply of STPs and not to purchase or use, thus preventing criminalising of young people who use STPs.
15. We acknowledge concerns regarding possible criminalisation of friends and whānau for small scale social supply of STP; to prevent this outcome, we recommend the Bill is amended to differentiate supply by corporate entities and persons, and that it re-classify the latter as an infringement offence.
16. For SFG enforcement, we suggest omitting the phrase 'knowingly or recklessly' in relation to proving the offence of supplying STPs. We note this intention will be difficult to establish and may hinder enforcement.
17. We recommend adding a power for the DGH to impose levies on retailers, distributors, importers or manufacturers of STPs and notifiable products, with revenue used to fund any additional costs of implementation and enforcement of the Bill's measures or to cover externalities imposed by STPs, such as the costs of environmental clean-ups.
18. We recommend tightening approval criteria (e.g. by requiring staff training in basic smoking cessation support and referral) for SVRs to clarify their primary purpose of selling products that may act as an alternative to using STPs and assist people who smoke to switch to a harm-reduced alternative.
19. We recommend adding specific criteria to ensure SVRs fulfil this purpose; for example, requiring that SVRs have information available about local smoking cessation services and the national Quitline, and have staff trained in delivering brief smoking cessation interventions and making referrals to cessation services.
20. We recommend monitoring the number and location of SVRs and enhancing enforcement of SVRs' compliance with regulations on sales to minors, with strengthened regulations introduced as necessary.
21. We recommend that the Bill should specify relevant targets, and monitor and report progress annually, to facilitate a comprehensive evaluation of the Smokefree Aotearoa 2025 Action Plan and measures included in the Bill.

22. We suggest consideration be given to adding mechanisms that could be triggered for implementation if monitoring and evaluation indicate further measures are necessary to reach the Smokefree Aotearoa 2025 goal for all peoples.

We would very much welcome the opportunity to present our submission to the Select Committee in person and answer questions in the domains of our expertise.

Abbreviations

DGH	Director General of Health
FDA	Food and Drug Administration
HTP	Heated tobacco product
SFG	Smokefree generation
STP	Smoked tobacco product
STR	Smoked tobacco retailer
SVR	Specialist vape retailer
WHO	World Health Organization

Introduction

We very much welcome the opportunity to submit on the Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill ('the Bill'). This submission has been prepared by University of Otago members of the ASPIRE 2025 Research Centre, a partnership between major research groups in Aotearoa carrying out tobacco control research to help achieve the Smokefree Aotearoa 2025 goal.

Tobacco remains a significant source of morbidity and mortality in Aotearoa (Figures 1 and 2). We believe the Bill may be the largest single legislated step ever proposed to improve health and health equity in Aotearoa and will be a landmark in public health and smokefree legislation in Aotearoa and beyond.

Figure 1 Healthy years of life lost in Aotearoa 2019 (from Global Burden of Disease estimates)[1]

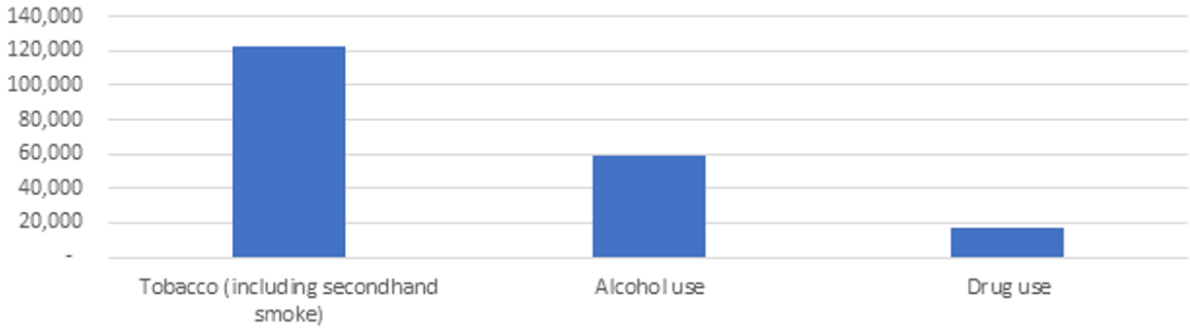
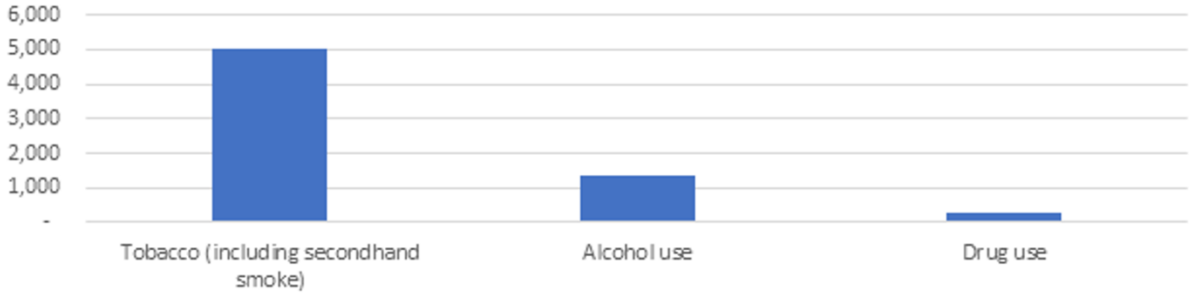


Figure 2 Premature deaths in Aotearoa 2019 (from Global Burden of Disease estimates)[1]

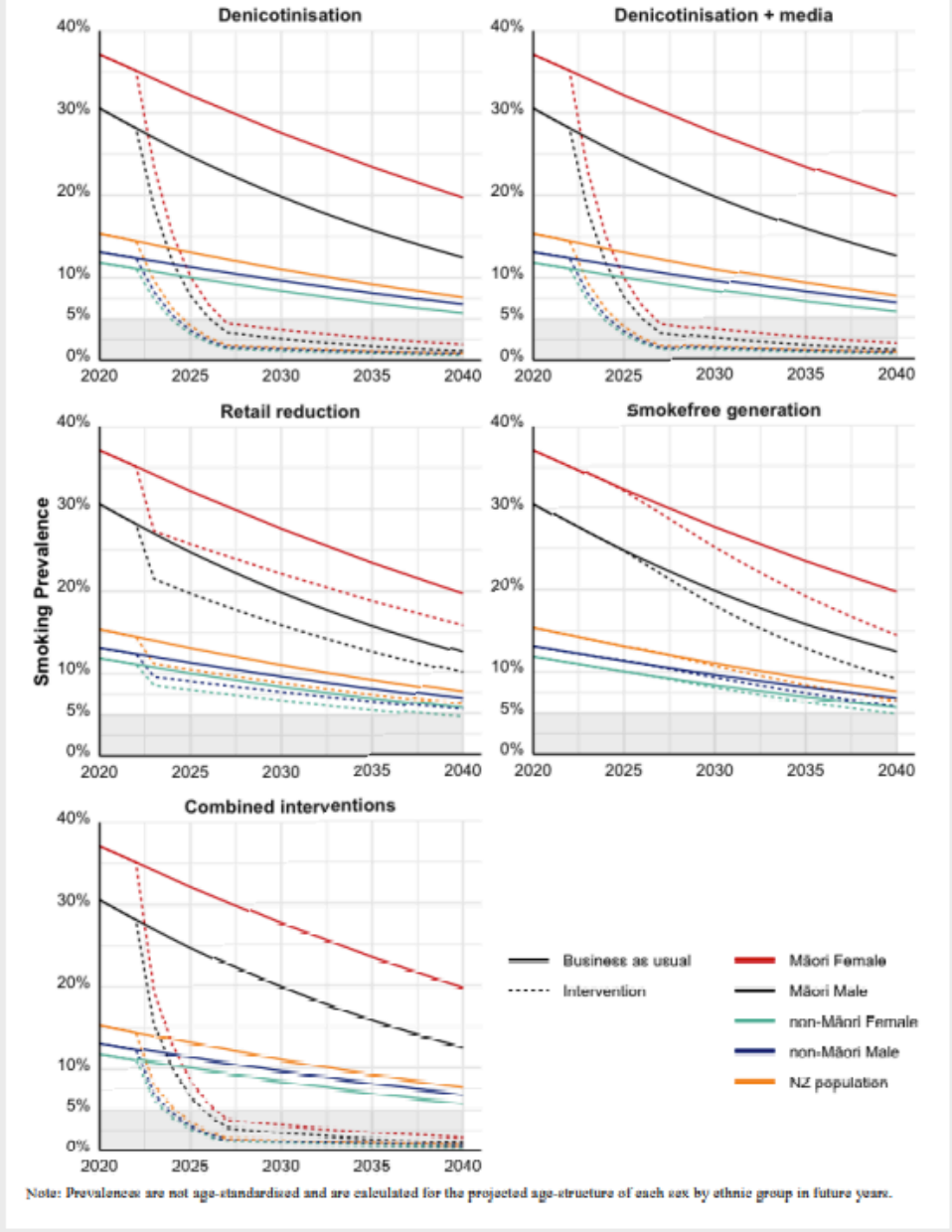


Modelling studies predict the Bill will save billions in dollars in health spending in coming decades;[2] the measures introduced should improve national productivity and citizens' incomes by hundreds of millions of dollars (e.g., from improved earnings and reduced expenditure on STPs).

We strongly endorse the Bill's commitment to implement three key policy measures (mandated denicotinisation, supply reduction, smokefree generation [SFG]). These bold, innovative measures have strong logical, theoretical and empirical support that provide confidence they will rapidly reduce the prevalence of STP use, thus supporting achievement of the Government's Smokefree Aotearoa 2025 goal. We also strongly endorse the Bill's movement beyond incremental 'business as usual' approaches to tobacco control policy.

In particular, we strongly support the mandated denicotinisation policy for all STPs, which modelling evidence estimates will result in rapid, equitable and very substantial reductions in smoking prevalence (Figure 3). [2 3]

Figure 3 Modelling for daily smoking prevalence in Aotearoa (20 years and older) overall and for Māori and non-Māori comparing business as usual to the introduction of denicotinisation, retail reduction and a smokefree generation.



Source: Ait Ouakrim et al, medRxiv 2022. [2]

The approach taken in the Bill and supporting Smokefree Aotearoa 2025 Action Plan[4] aligns with increasing international momentum to go beyond 'business as usual' approaches to tobacco control. For example, the US Food and Drug Administration (FDA) recently proposed introducing a mandated denicotinised tobacco policy;[5] Malaysia and Denmark have proposed smokefree or nicotine-free generation policies,[6 7] and the UK Khan review recommended a comprehensive strategy to minimise STP use ,including introducing a SFG and freezing the tobacco market.[8]

We also commend implementing the three key measures as part of a comprehensive strategy supported by outlined in the accompanying Smokefree Aotearoa 2025 Action Plan. These include enhanced targeted cessation support, mass media campaigns, and community-led smokefree interventions. These additional measures will support implementation, maximise the positive impacts of the key measures included in the Bill, and ensure people who smoke have access to encouragement and support to quit smoking. It will be important to develop a comprehensive and appropriately resourced implementation plan for each measure.

The Bill focuses on strengthening the regulation of STPs; we strongly support that priority. However, we note widespread concerns about the recent increase in vaping among rangatahi and believe the Bill could be amended to reinstate the previous Act's purpose to protect young people from taking up vaping. We strongly believe that reviewing the vaping regulations should be a priority for future work.

We also note the need to develop and implement a strategic and appropriately resourced approach to monitoring, evaluation and enforcement, as the Smokefree Aotearoa 2025 Action Plan proposed. This approach will ensure measures included in the Bill are fully effective; furthermore, detailed monitoring and robust evaluation will enable rapid detection and appropriate responses to any unintended adverse impacts, such as growth in the illicit STP market. We are concerned that the current capacity and capability of the smokefree enforcement workforce is insufficient to ensure appropriate enforcement and therefore recommend reviewing and enhancing the capacity and capability of the smokefree enforcement workforce.

Although we strongly support the Bill and its key measures, we believe several aspects could be further strengthened to maximise the probability of achieving the Smokefree Aotearoa 2025 goal. We have commented on these and made accompanying recommendations on each of the following aspects of the Bill:

- General approach, over-arching comments and recommendations (p7)
- Meeting the Crown's commitments to Honouring Te Tiriti o Waitangi (p9)
- Purposes of the Bill (p11)
- Smoked tobacco product regulation including mandated denicotinisation (p15)
- Reducing the number of smoked tobacco product retailers (p20)
- Introducing a smokefree generation policy (p25)
- Imposition of levies (p29)
- Record-keeping (p29)
- Specialist vape retailers (p30)
- Offence provisions (p31)
- Monitoring, evaluation and review (p32)

We have also included four appendices with (1) suggestions for revised purposes (p34); (2) information about the illicit tobacco market in Aotearoa (p35); (3) an example of outlet mapping in relation to schools and neighbourhood deprivation level (p38) and (4) detailed comments and suggestions for offence provisions rewording (p39).

Recommendations

1. We recommend developing and implementing a detailed strategy for introducing the supporting 'business as usual' measures described in the Smokefree Aotearoa 2025 Action Plan as soon as practicable.
2. We recommend reviewing and enhancing the capacity and capability of the smokefree enforcement workforce.

General approach, over-arching comments and recommendations

Comments

In this section, we make general and over-arching comments, and associated recommendations, about the timeline. We also review the balance between legislation and regulatory implementation and examined how heated tobacco products (HTPs) are addressed.

(i) Timelines and sequencing

We believe it is critical that the timelines and sequencing of the Bill's key measures be reconsidered. Specifically, we suggest expediting the timeline to implement denicotinisation of STPs so this measure occurs before implementing retail restrictions. Denicotinisation will rapidly and substantially reduce smoking prevalence, and thus consumption and demand for tobacco products. As demand for STPs declines, retailers will recognise the diminishing contribution tobacco products make to their business and thus realise the need to replace STPs with other products. Sequencing the measures in this way will likely make retailer reduction more acceptable and easier to implement.

(ii) Balance between the statute and post-enactment regulations

We are very concerned about over-reliance on regulations to set out nature and scope of the three key measures and how they will be implemented. We believe more of these key details should be specified in the Bill.

We agree that the Director General of Health (DGH) should have the authority to introduce regulations to implement some aspects of the Bill, and understand post-enactment regulations allow for greater flexibility. However, regulatory decisions made by the DGH can be legally challenged, which could greatly delay or prevent implementation of key measures and thus diminish the likelihood the Smokefree Aotearoa 2025 goal will be realised. Such challenges would be particularly problematic if they came from the tobacco industry or stakeholders with a vested financial interest in selling tobacco, and would contravene the principles and provisions of the Te Tiriti o Waitangi (see below).

It is therefore critical that key details, such as the amount by which retail access and nicotine content in tobacco should be reduced, are stated in the Bill rather than deferred to post-enactment regulations. Flexibility is unnecessary for some details, such as setting the maximum levels of nicotine in STPs, as there is substantial research evidence about the level likely to have the greatest impact on reducing the addictiveness of STPs and hence smoking prevalence (see "Suggestions to Strengthen Provisions for Denicotinisation" below).

We have suggested where the Bill could stipulate specific provisions in relevant sections below.

(iii) Scope of Bill: addressing Heated Tobacco Products (HTPs)

We are concerned that the Bill does not adequately regulate HTPs. These devices heat tobacco sticks to release nicotine-containing emissions that are then inhaled. Currently, HTPs are not included in the STP definition in the Bill (rather they are 'notifiable products', i.e., classified together with vaping products) and hence are not subject to the three key measures the Bill introduces. We believe HTPs **must** be regulated in the same way as STPs.

Philip Morris International first introduced HTPs to the New Zealand market when they launched HEETs, the sticks used in their 'IQOS' devices around 2017. Philip Morris International claims that HTPs are a "smoke-free" product that does not involve combustion and thus does not produce the toxic smoke that is so harmful to people who smoke.[9] Other brands of HTPs (e.g., BAT's 'glo') are not generally available yet in New Zealand.

The World Health Organization (WHO) describes HTPs as heating tobacco *"without reaching ignition to produce an emission containing nicotine and other chemicals"*.[10] Unlike smoking, where nicotine is

aerosolised by igniting and burning tobacco and where temperatures of up to 900°C may be reached, HTPs volatilise nicotine at lower temperatures (around 350°C, through to 550°C). It is plausible that lower temperatures will result in the release of emissions that have fewer toxicants or where toxicants are present in smaller amounts than in smoked tobacco smoke. However, because HTPs are a novel tobacco product, research evidence is limited and comes mainly from studies funded or carried out by the tobacco industry (which are therefore particularly subject to bias).

The available evidence suggests HTPs are likely to be less harmful than STPs but more harmful than vaping. A recent Cochrane systematic review concluded *"…there was moderate-certainty evidence that users of heated tobacco have lower exposure to selected toxicants and carcinogens than cigarette smokers so it is plausible that HTPs are associated with less adverse health effects than smoking*."[11] Recent reviews of emissions and biomarker studies came to a similar conclusion.[12] [13] However, uncertainty remains because there are no long-term epidemiological studies investigating the health impacts of HTPs, leaving the health benefits of switching from smoking to HTPs unclear.

Evidence comparing HTPs and vaping products like e-cigarettes is even more limited, but reviews and expert commentaries generally conclude that HTPs are likely to be more harmful than e-cigarettes. For example, Dusautoir et al. found higher levels of polycyclic aromatic hydrocarbons and carbonyls in HTPs compared to e-cigarettes.[14]

In addition, there is no evidence from randomised controlled trials that HTPs use is associated with increased STP cessation.[11] In markets where HTPs have gained substantial market share (e.g., Japan and Korea), rising prevalence has not accelerated declines in smoking prevalence (although STP consumption has reduced in Japan[15]) and dual use (continued smoking and concurrent use of HTPs) is the most common behaviour associated with HTP use.[16] [17] This outcome is highly problematic, given reduced smoking brings far fewer health benefits compared to complete cessation.[18]

Furthermore, HTPs have a low market share in Aotearoa (i.e., have not had wide uptake compared to other alternatives to smoking) and are not commonly used currently as cessation aids. For example, preliminary data [i] from the ITC/EASE study of 1,280 people who smoke or recently quit (collected from October 2020-February 2021) found that while around 27% were daily vapers, only about 5% used HTPs daily. Among participants who tried to quit or who had quit in the last two years, approximately 57% reported using e-cigarettes on their last or current quit attempt compared to about 7% who reported using HTPs. Finally, HTPs are priced as a premium product and the devices are more expensive than most vaping devices (e.g., IQOS Duo starter kit is $139); [19] this pricing strategy means HTPs are unlikely to appeal to disadvantaged people who smoke, a population group with markedly higher smoking prevalence. Together with the absence of RCT data attesting to HTPs' efficacy as cessation aids, the ITC findings strongly suggest HTPs are unlikely to make a significant contribution to the equitable achievement of the Smokefree Aotearoa 2025 goal.

Given the wide availability of a diverse range of vaping products, the likely greater harmfulness of HTPs compared to vaping, the lack of evidence that HTPs assist smoking cessation, the limited uptake of HTPs in Aotearoa, and the uncertainty that HTPs will help reduce smoking prevalence, we believe there is little or no benefit in exempting these products from the denicotinisation, retailer restrictions and SFG policies. We therefore consider that there is a strong public health rationale for HTPs being included in the definition of STPs and treated as STPs for regulatory purposes.

For the remainder of this document, where we refer to STPs we assume that this abbreviation also includes HTPs unless stated otherwise.

[i] Figures quoted from the ITC/EASE study are from preliminary analyses and are pending final analysis – we hope to have more definitive figures available by the time of oral submissions.

Recommendations

1. We strongly recommend expediting the introduction of denicotinised tobacco so this measure is fully implemented before the retail restriction policies come into effect.
2. We recommend that the Bill (rather than post-enactment regulations) specifies the number of retail outlets that will be permitted and the maximum level of nicotine that will be allowed in STPs. For detail See "Suggestions to Strengthen Provisions for Denicotinisation" below.
3. We recommend including HTPs in the definition of STPs, to ensure HTPs are regulated in the same way as STPs and are subject to mandated denicotinisation, constraints on retail availability and the SFG policy.

Meeting the Crown's commitments to honouring Te Tiriti o Waitangi

Comments

We strongly support the commitment to honouring Te Tiriti o Waitangi made in the Bill. We also acknowledge and commend the Smokefree Aotearoa 2025 Action Plan's key outcomes, which include eliminating inequities in smoking and smoking-related illness. We strongly support Focus area 1 of the Smokefree Aotearoa 2025 Action Plan, which will ensure Māori leadership and decision-making at all levels. However, we believe there are places where commitment to Te Tiriti should be strengthen and we have some suggestions about how Te Tiriti should be addressed within the Bill.

(i) Exclusive use of Te Tiriti o Waitangi in the Bill

We acknowledge the Crown's specific obligations to Te Tiriti o Waitangi (Te Tiriti) in relation to tobacco related harm and its significance as stated in the draft Bill. As highlighted in the Bill, we note additional Crown obligations to protect Māori from tobacco-related harm and meaningfully engage with Māori as a signatory to the Framework Convention on Tobacco Control (Preamble and Article 4/2c) and the United Nations Declaration on the Rights of Indigenous Peoples. Finally, we note the whakapapa of this legislation and the 42 Recommendations in the Māori Affairs Select Committee report to the Government in 2010. [20]

Both te reo Māori and English names for Te Tiriti o Waitangi are used in the Bill's text. As is widely known, two versions of Te Tiriti were signed during 1840: the original text in te reo Māori; and an English version. There is also an English translation of the Māori text. The original Māori and English versions substantially differ in their interpretation of rights accorded to Māori. We note previous political debates related to Te Tiriti (e.g., the Foreshore and Seabed Act) referred to both versions, thus creating ambiguity about the Government's remit in passing legislation affecting Māori. Under international rule, *contra proferentem* applies and the te reo Māori text of Te Tiriti should take precedence. For the Bill, we strongly believe that Te Tiriti should only be referred to in its te reo Māori form to make it clear that any references to obligations to Māori in the Bill are clearly linked to the te reo Māori text.

(ii) Reference to provisions rather than principles of Te Tiriti

The Bill refers to *giving "…effect to the principles of Te Tiriti o Waitangi…"*. A principles perspective on Te Tiriti was highlighted in the Royal Commission on Social Policy report (1988). [21] This perspective provides important insights into understanding Te Tiriti in a contemporary context. However, there are other perspectives (e.g., provisions) that extend our understanding of Te Tiriti. In particular, these perspectives highlight the importance of enabling Maori self-determination. We suggest that references to "principles" are amended to "principles and provisions" and reference made to Crown commitments to honouring Te Tiriti.

(iii) Consistent reference and commitment to Te Tiriti o Waitangi throughout the Bill's text

The Bill refers to Te Tiriti o Waitangi obligations across the proposed measures inconsistently. Section 3AB of the Bill states "*In order to provide for the Crowns intention to give effect to the principles of Te Tiriti o Waitangi/the Treaty of Waitangi...".* However, the statements relating to Te Tiriti that follow appear to be specifically related to clauses in the Bill about reducing retail access to tobacco. There do not appear to be any references to Te Tiriti in other key aspects of the Bill including creating a SFG, regulating tobacco constituents or reducing nicotine content in tobacco. There is reference to the DGH taking into consideration the risks and benefits of regulating constituents for Māori, but no explicit requirement to engage with Māori.

We note that Māori advocacy for a tobacco endgame in the mid-2000s and the subsequent 42 MASC recommendations highlighted the need to focus on limiting the supply and addressing the nature of tobacco products (including limiting the level of nicotine to reduce addictiveness) as well as protecting rangatahi. [20]

We believe that the requirement for Māori engagement should be included in all aspects of development and implementation of all the main measures included in the Bill and, in particular, those measures that will have a significant impact on Māori, such as mandatory denicotinisation and the SFG policy.

(iv) 'Engaging' rather than 'consulting' with Māori

Te Tiriti related clauses in the Bill commonly use the term 'consultation' with Māori. In the past consultation process with Māori have been characterised by meeting with Māori stakeholders, hearing their views, but failing to take these views into account in decision-making. This process does not reflect true Te Tiriti partnerships or make best use of Māori potential to support the implementation of a Bill that will see the Smokefree Aotearoa 2025 goal achieved. We believe the appropriate term should be 'engage' which implies active Māori partnership and participation in all aspects of decision making.

(v) Including clear reference to protecting rangatahi from vaping in the Bill's purposes

As noted elsewhere in this submission, the purposes of the Smokefree Environments Act have been substantially modified in the current Bill; in particular, references to protecting rangatahi from vaping have been removed.

We note that this approach locates smoking as a (Western) biomedical health issue. Māori models of health view harm from nicotine addiction in much more holistic terms (including how addiction impacts whānau and wairua). In this sense, the Bill does not fully recognise Māori perspectives in relation to addressing smoking and nicotine product use. While vaping may be appropriate for some people who smoke and cannot quit (and we acknowledge there are a diverse perspectives on this issue), we are alarmed at the rapid rise of experimentation and daily vaping among rangatahi. Kei te tika te korero o tatou tupuna: Mō tātou, ā, mō kā uri ā muri ake nei (for us and our children after us). We must ensure that entrenching vaping among rangatahi of today and in future generations is not unintended legacy of the Bill.

We therefore strongly recommend that the purposes and provisions within the legislation should include reference to protecting rangatahi from taking up vaping and that there should be a comprehensive review of the vaping legislation and regulations after the Bill has passed. As part of this review we believe consideration should be given to modifying the 'Smokefree Generation' measure to a 'Nicotine-Free Generation' measure (in which people born after a specified date are never legally able to be sold any nicotine product) either now or at a future date (see p28 for detailed recommendation).

(vi) Ensuring the structures for Government engaging with Māori reflects a true Te Tiriti o Waitangi partnership

We strongly support the establishment of the Te Aka Whai Ora (the Māori Health Authority) and its role in overseeing implementation of the Smokefree Environments Amendment Act. However, Te Aka Whai Ora is an agent of the Crown and therefore care should be taken not to imply it is a Māori 'partner' in relation to Te Tiriti (particularly as the ultimate authority in this relationship still resides in the DGH).

Therefore, we believe the structure for engaging with Māori should be amended to better reflect a true Te Tiriti partnership. A revised structure could be achieved through changing the role of the Te Aka Whai Ora in relation to the Bill to facilitating Te Tiriti partnerships and establishing an independent Māori governance group to provide input into the development of any regulations and the overall implementation and evaluation of the legislation. This group could evolve from the Māori taskforce that has been providing input into the Bill during 2022. The group could then engage with iwi-Māori partnership boards or other Māori authorities and stakeholders as the need arises.

We are also concerned that some political parties have indicated they will disestablish Te Aka Whai Ora if elected. If this change eventuated, it would create a 'gap' in the legislation that could potentially affect Māori engagement. As a safeguard, we recommend establishing an independent Māori governance group that is formally recognised in the legislation (including its makeup, roles and term) to help mitigate this risk. This group could oversee implementation of the legislation, including development of any regulations, and related policies or actions.

Recommendations

1. We recommend that the Bill should refer only to "Te Tiriti o Waitangi" (and remove references to "Treaty of Waitangi").
2. We recommend that references to "principles" are amended to "principles and provisions".
3. We recommend that references to Te Tiriti obligations, and in particular the requirement for Māori engagement, should be included for all aspects of the Bill, particularly for the three key measures (retailer reductions, mandated denicotinisation and SFG policy) it includes.
4. We recommend that "consultation" should be replaced with "engagement" throughout the text of the Bill.
5. We recommend that the purposes of the Bill should include explicit reference to protecting rangatahi from vaping.
6. We recommend that the Bill formally establishes and resources an independent Māori governance group to oversee implementation of the legislation, including development of any regulations, policies or actions.

Purposes of the Bill

Comments

We note that the purposes of the Bill now differ in several substantive ways from the purposes outlined in the 2020 Act (see table 1). In particular, the purposes relating to controlling vaping have been greatly reduced and made less specific with two major changes: first, clause 5 replaces existing Section 3A(1) with a new set of purposes; and second clause 27 deletes section 49 of the existing Act (the purposes of the packaging and labelling requirements) completely, with no replacement.

The proposed new purposes in Section 3A of the Bill greatly weaken commitments to protect young people from taking up vaping outlined in the principal Act (2020). We contrast the Bill's purposes with those of the existing Act in table 1. Specifically, we note that the Bill no longer has specific purposes of discouraging or preventing children and young people from taking up vaping, preventing the

normalisation of vaping, supporting smokers to switch to less harmful regulated products, or encouraging people to stop vaping and not resume smoking or vaping (see highlighted sections in table 1). The Bill only includes a non-specific purpose of regulating notifiable products in a way that seeks to minimise harm. References to smokeless tobacco and HTPs are also now deleted.

We also note that the Parliamentary Counsel Office's explanatory note (General policy statement) clearly states the Government's commitment to reaching the Smokefree Aotearoa 2025 goal, and the three priority strategies for realising this goal. The general policy statement also states that '*the single broad policy implemented by the amendments in this Bill is to achieve the Smokefree 2025 goal*'. However, the purposes sections in Part 1, Amendments to principal Act of the Bill at 3A do not include over-arching aims relating to the Smokefree Aotearoa 2025 goal.

We note that having clear and detailed purposes guides the evaluation of the Bill and supports enforcement by providing a clear rationale and justification for enforcement actions.

We recognise that it makes sense to consolidate the purposes of the new legislation, so that there is only one set rather than two. We strongly recommend including an overarching statement(s) about the purpose(s) of the Bill and amending the Bill to include a purpose about protecting rangatahi from taking up vaping.

In Appendix 1 (p34), we draw on purposes from the present Act to suggest detailed revised purposes for the Bill. We propose two over-arching and accompanying specific detailed purposes with respect to STP (including HTPs) regulation, and vaping and other non-combusted nicotine products.

Recommendations

1. We recommend revising the present draft "purposes" (as set out in clause 5 amending section 3A), so that at a minimum they reflect the over-arching aims of the Bill and that the purposes of protecting youth from vaping should be reinstated: see Appendix 1 (p34) for suggested wording.

Table 1 Comparison of general purposes of 2020 Act and 2022 Bill

2020 Smokefree Environments and Regulated Products (Vaping) Amendment Act	2022 Smokefree Environments and Regulated Products (Smoked Tobacco) Amendment Bill
3A Purposes of this Act (1) The purposes of this Act are, in general, as follows: (a) to reduce the exposure of people who do not themselves smoke to any detrimental effect on their health caused by smoking by others; and (b) to prevent the normalisation of vaping; and (c) to regulate and control the marketing, advertising, and promotion of regulated products (whether directly, including through the appearance of regulated products and packages, or through the sponsoring of other products, services, or events) in order to improve public health by: (i) discouraging people, especially children and young people, from taking up smoking; and (ii) discouraging non-smokers, especially children and young people, from taking up vaping or using smokeless tobacco products; and (iii) encouraging people to stop smoking, vaping, or otherwise using regulated products; and (iv) discouraging people who have stopped smoking, vaping, or otherwise using regulated products from resuming smoking, vaping, or using regulated products; and (ca) to support smokers to switch to regulated products that are significantly less harmful than smoking; and (d) to regulate the safety of vaping products and smokeless tobacco products; and (e) to monitor and regulate the presence of harmful constituents found in regulated products and their emissions; and	**Section 3A amended (Purposes of this Act)** The purposes of this Act are— (a) to provide for the regulation of smoked tobacco products— (i) to prevent the harmful effect of other people's smoking on the health of others, and especially on young people and children; and (ii) to significantly reduce the retail availability of smoked tobacco products; and (iii) to prevent young people, and successive generations, from ever taking up smoking; and (iv) to reduce the appeal and addictiveness of smoked tobacco products; and (v) to restrict all forms of advertising and promotion; and (vi) to reduce disparities in smoking rates and smoking-related illnesses between New Zealand population groups, and in particular between Māori and other groups; and (b) to provide for the regulation of notifiable products in a way that seeks to minimise harm; and (c) to give effect to certain obligations and commitments that New Zealand has as a party to the WHO Framework Convention on Tobacco Control, done at Geneva on 21 May 2003.

(f) to give effect to certain obligations and commitments that New Zealand has as a party to the WHO Framework Convention on Tobacco Control, done at Geneva on 21 May 2003. **Section 49 [now deleted) Purposes of Packaging and labelling requirements** The purposes of this Part are **(**a) to reduce the social approval of smoking, particularly among children and young people: (b) to reduce the appeal of vaping and the use of heated tobacco products for non-smokers, particularly children and young people: (c) to require the standardised appearance of regulated products and their packages (including messages and information) in order to— (i) reduce the appeal of smoking, particularly for young people; and (ii) further reduce any social and cultural acceptance and approval of smoking; and (iii) reduce the appeal of vaping and use of heated tobacco products for non-smokers, particularly for children and young people; and (iv) make warning messages and images more noticeable and effective; and (v) reduce the likelihood of consumers acquiring false perceptions about the harmful effects of smoked tobacco products, vaping products, and smokeless tobacco products. (d) to discourage non-smokers, particularly children and young people, from vaping and using heated tobacco products: (e) to reduce some of the harmful effects of tobacco products on the health of users by monitoring and regulating the presence of harmful substances in the products and in tobacco emissions (f) to facilitate the harmonisation of the laws of New Zealand and Australia relating to the labelling of smoked tobacco products (including, without limitation, requirements relating to the display of health messages).	

Smoked tobacco product regulation including mandated denicotinisation

Comments on mandated denicotinisation

(i) Summary of Bill's provisions

The Bill requires (Part 3 section **57H**) that the Minister, within 21 months of commencement, recommends regulations that limit the quantity of nicotine in any STP and outlines a method of determining whether those limits have been exceeded.

(ii) Rationale and evidence

Policy impact: We strongly support this measure, which we believe that it is the single most important intervention included in the Bill. There is very strong evidence to suggest this measure is likely to result in rapid and profound reductions in smoking prevalence by greatly reducing smoking uptake, increasing smoking cessation, and reducing relapse to smoking among people who have quit smoking.

Theory and logic both suggest mandated denicotinisation will minimise the addictiveness and appeal of STPs, greatly accelerate the decline in smoking prevalence, and do so in equitable way. The tobacco industry has long known that nicotine is the main cause of the addictiveness of smoking and that people who smoke do so mainly to obtain nicotine.[22 23] More than 50 years ago, they recognised that, without nicotine, they would lose the hold they have over people who smoke:

> "To lower nicotine too much might end up destroying the nicotine habit in a large number of consumers and prevent it from ever being acquired by new smokers."
>
> **Source**: Quote from British American Tobacco Company internal document, June 1959 [24]

Evidence supporting denicotinisation: Two recent authoritative reviews summarise the key evidence.[25 26] These describe numerous randomised controlled trials and other studies that reported people who smoke and who are provided with denicotinised cigarettes find these products less appealing and satisfying, and are more likely to make quit attempts and stop smoking. One of the largest of these trials was conducted in Aotearoa and found increased quit rates (33% at 6 months) among Quitline callers randomised to receiving denicotinised cigarettes in addition to the normal Quitline intervention. The study found equal effectiveness for Māori and non-Māori.[27]

Evidence continues to accumulate rapidly, with similar findings from multiple settings among diverse populations. An example is a randomised controlled trial published this year which recruited people who smoke with current or historical anxiety or depression and no intention to quit within six months.[28] The trial found that, compared to a group provided with usual strength cigarettes, the group randomised to receive denicotinised cigarettes smoked fewer cigarettes, had lower levels of smoking-related toxins, displayed less evidence of dependence, made more quit attempts, and were over four times as likely to quit after five months of follow-up. Furthermore, there was no difference in several indicators of stress, anxiety and depression between the two groups; these latter findings suggest that denicotinisation will not result in excessive stress or threaten the well-being of people who smoke, as has been mooted. [29]

Further evidence comes from studies that examine how people who smoke think they will respond if mandatory denicotinisation is introduced. For example, preliminary analyses of participants in the TAKe study, a cohort study of Māori people who smoke, found over half said they would quit smoking (40%) or switch to e-cigarettes (14%) if denicotinised cigarettes were the only available STPs.[30] Similarly, preliminary data from the New Zealand ITC study (which surveyed almost a thousand people

who smoked between October 2020 and February 2021), found that, if mandated denicotinisation was introduced, just over a quarter (27%) anticipated that they would quit smoking and 20% believed they would cut down on their smoking. Of those anticipating quitting, around half thought they would quit entirely and the other half thought they would switch to vaping.[31] A US study found that among people who have used denicotinised cigarettes an even higher proportion (around half) anticipate quitting if denicotinised products were the only cigarettes available.[32]

Modelling studies add more evidence. A preliminary modelling study[3] and a more sophisticated subsequent study[2] have both projected denicotinisation to dramatically and rapidly reduce daily smoking prevalence and reduce inequities in smoking prevalence if implemented in Aotearoa. For example, the more recent modelling study predicts that denicotinisation will result in Māori smoking prevalence falling from 32% in 2022 to 7% in 2025, with below 5% prevalence being achieved in 2026 for males and 2027 for females (see Figure 3).[2] This study also found that denicotinisation is likely to result in substantial reductions in Māori vs non-Māori health inequities.

Policy implementation: Denicotinisation is technically feasible[33] and existing products are available internationally (https://www.fda.gov/news-events/press-announcements/fda-permits-sale-two-new-reduced-nicotine-cigarettes-through-premarket-tobacco-product-application). There is also evidence that the policy is acceptable, with high levels of support, including from around three quarters (76%) of people who smoke in Aotearoa.[31]

Aotearoa is a highly favourable context to implement mandated denicotinisation because reasonably comprehensive and effective smoking cessation support is available for people who smoke who do not wish to, or cannot, quit nicotine products. In addition, less hazardous non-combustible products (e.g., subsidised nicotine replacement therapy and vaping products) are widely available (with vaping products typically having a much lower cost per dose of nicotine obtained than STPs).

The Smokefree Aotearoa 2025 Action Plan and other measures included in this Bill will further enhance the supportive context for the denicotinisation policy. Other robust policies outlined in the Action Plan include reduced retail availability of tobacco products and the SFG policy, and enhanced support for people who smoke (e.g., enhanced targeted smoking cessation support and community-based smokefree interventions). We urge the rapid implementation of those plans so that people who smoke have access to high quality support to quit when the denicotinisation policy is implemented. Because the policy is anticipated to have a dramatic impact on increasing quitting, cessation support services must be appropriately resourced and staffed to cope with the surge in demand.

Addressing concerns about denicotinisation: We note that some concerns have been raised about mandated denicotinisation of STPs, including in some contributions to the First reading debate for the Bill. We believe these concerns are contradicted by the scientific evidence on denicotinisation and some may reflect deliberate misinformation propagated largely by the tobacco industry and its allies.

For example, claims denicotinisation will increase harm through compensatory smoking are contradicted by the overwhelming evidence that people provided with denicotinised cigarettes smoke **less** and have lower levels of harmful toxins – provided nicotine levels are reduced to minimal levels (≤ 0.4mg nicotine/g tobacco).[25 26]

Nor is there robust evidence that denicotinisation will result in a greatly increased black market in tobacco products. Tobacco companies routinely raise concerns over illicit tobacco in response to almost every evidence-based smokefree policy measure; their claims typically prove to be false or greatly exaggerated. For example, our repeated discarded pack collections (see Appendix 2 for detail, p35) in 2008/9, 2013 and 2021/22 reported that the proportion of smuggled packs remained between 3-6% despite substantial increases in tobacco excise tax from 2010 to 2021 and the introduction of other tobacco control policies such as standardised (plain) packs, which the industry claimed would greatly increase smuggling. In addition, assuming denicotinisation results in a rapid decline in smoking prevalence, this will markedly reduce the size of the overall tobacco market, and hence also the black

market. Finally, the most appropriate response to any increase in illicit trade is to enhance monitoring and enforcement, which is the approach adopted in the Smokefree Aotearoa 2025 Action Plan. As an island nation with strong border controls, Aotearoa is particularly well placed to minimise the illicit tobacco trade. Indeed, it has a first in the world ranking (equal with Sweden) in regard to this capacity (see Appendix 2, p35).

Nor is denicotinisation akin to prohibition; STPs will still be available (albeit denicotinised) and alternatives such as e-cigarettes will provide access to alternative nicotine products. Furthermore, most people who smoke regret smoking and make multiple attempts to quit.[31] Prohibition-type arguments for denicotinisation therefore fail on even the most rudimentary grounds as the logical parallel between alcohol prohibition and denicotinisation overlook crucial differences in: (i) behaviours (casual for most alcohol drinkers vs addicted for people who smoke); (ii) desire (to continue for most people who drink alcohol vs to quit for most people who smoke); and (iii) policy effect (no alcohol products available vs alternative nicotine products widely available). Furthermore denicotinisation is fully justifiable given the profound harms smoking causes, the enormous health burden it imposes on society, and the extreme addictiveness of STPs.

(iii) Suggestions to strengthen provisions for denicotinisation

We believe that the denicotinisation provisions could be strengthened in several ways. First, we suggest expediting the timetable so that regulations must be introduced within 12 (not 21) months of Royal Assent, and that an implementation date is set (e.g., before the end of 2023 or as soon as is feasible). Given the technical feasibility of producing denicotinised products and the international availability of these products, there is no reasonable argument that the tobacco companies operating in Aotearoa need a substantial lead-in period to adjust to the new policy.

The Bill does not currently specify a maximum level of nicotine under the new regulations. This is a critical omission which overlooks robust scientific evidence supporting a level of ≤0.4mg /g tobacco. Authoritative international reviews recommend this level based on clear evidence that it eliminates any compensatory smoking and is associated with increased quitting. [25 26]

Best practice also supports an immediate rather than gradual reduction in nicotine content.[26] As a result, we recommend specifying a date after which only denicotinised STPs may be legally sold.

We note it will be essential that an appropriate testing regime is in place before the introduction of the nicotine reduction requirements. We believe that core features of this testing regime should be specified in the Bill and not in regulations, and that it is imperative the testing regime is independent of tobacco companies.

We are concerned the Bill currently proposes manufacturers and importers undertake testing (clause 57F (2)). Because tobacco companies have historically manipulated evidence regarding their products, it is essential that all testing is undertaken by an independent, Government approved, agency with all testing undertaken at the tobacco manufacturers' or importers' expense.

We believe that testing should involve regular (e.g., 3-monthly initially, then 6-monthly after the first year) testing of STPs sourced from STP retail outlets (rather than product supplied direct to the tester by the manufacturer or importer), and that the DGH should be required to establish a suitable system at least six months before mandated denicotinisation comes into effect.

Recommendations

1. We strongly recommend that the timetable for introducing regulations prescribing the limits for nicotine quantities in any STP is expedited and that the Bill specifies regulations must be introduced within 12 (not 21) months of Royal Assent. The Bill should also specify a date by which this policy must be implemented (e.g., before the end of 2023 or as soon as practicable if end of 2023 is not feasible).

2. We recommend three additions to the Bill: (i) that a maximum level of nicotine (≤0.4mg /g tobacco) is specified in the Bill itself together with enabling regulatory powers for the DGH to lower the approved level further; (ii) that an immediate rather than gradual reduction in nicotine content should be specified; and (iii) that the timeframe for establishing the testing system be specified along with relevant offences if nicotine levels exceed the 0.4 mg /g of tobacco limit.
3. We recommend that the Bill specifies that the DGH introduces a system for regular testing of the nicotine levels of each manufacturer's or importer's products by an independent, approved agency at the manufacturer's or importer's expense.

Comments on other aspects of smoked tobacco product regulation

(i) Summary of Bill's provisions

Section 82B provides powers to introduce regulations for requirements for STPs including prohibiting constituents, prescribing limits for constituents or emissions including limits on nicotine levels, and prescribing 'safety standards' for STPs. Part 3 Section 52(b) proposes that STPs are required by regulations to list constituents and their respective quantities present in the product's emissions. Part 3 Sections 57A-G and 69A requires that all STPs must be approved for sale, manufacture, import or supply by the DGH, who can only approve an STP if it has been tested in accordance with regulations, and does not include prohibited constituents or levels of constituents above proscribed levels.

(ii) Rationale and evidence

Policy impact: We strongly support introducing powers to regulate STP constituents and emissions, and the requirement to list STP constituents and for STPs to be approved for sale after appropriate testing.

Up to now, there has been minimal regulation of the design and constituents of STPs, which represents a major omission in smokefree policy, particularly given the highly addictive and toxic nature of these products. Effective legislation to address this omission would provide the necessary flexibility to regulate constituents and design features of existing and future STPs so these are less appealing, harmful and addictive.

We note that some current STP design features have potentially very serious adverse consequences for health and the environment and believe there is a strong case for prohibiting these features. This issue was noted in the Smokefree Aotearoa 2025 Action Plan. For example, filters do not reduce the harms caused by smoking STPs, but instead increase product appeal, foster and sustain misperceptions,[34] and have major adverse environmental impacts. [35 36]

Other highly problematic design features are flavour capsules in the filters of manufactured cigarettes which can be crushed to release an appealing taste during smoking. These products have been found to appeal particularly to young people.[37] A study conducted in Aotearoa found that cigarettes containing flavour capsules are more appealing to young people who do not smoke than to those who currently smoke.[38]

In addition, because the Bill and associated Smokefree Aotearoa 2025 Action Plan aim to minimise smoking, and the use of and demand for STPs, there can be no valid justification for introducing new STPs, new brands and brand variants, or new design features. As noted above, tobacco companies have used design innovations to develop and market products that falsely appear less hazardous (e.g., filters), hence deterring cessation or that appeal to and potentially help recruit young people to smoking (e.g., flavour capsule cigarettes). In a recent development, Philip Morris International introduced a new low price 'cigarillo' brand to Aotearoa, potentially undermining the impact of regular tobacco excise increases on reducing the affordability of STPs.[39]

Policy implementation: With regard to use of the words 'safety standards', we think this is inappropriate for an inherently highly hazardous product; the word 'standards' is sufficient.

We support the stipulation to list STP constituents in principle, but we note that STPs have many constituents, both in the product and in emissions created by product use. We would be concerned if requirements were introduced to list large numbers of constituents/emissions as such a requirement could result in lists that were in a small font size and thus difficult to read and/or could encroach on or distract from the pictorial warnings on packs. A long list of constituents may also not be particularly meaningful for most people. We suggest further clarification may be needed so that this requirement is practicable and addresses the most important constituents, and does not disrupt on-pack warnings or cessation information. However, we strongly support requiring manufacturers to list the constituents of all their STPs and provide this information in annual returns to the DGH.

We believe that powers to require manufacturers and distributors to list key product constituents and supply this information annually to the DGH should also apply to all other notifiable products, including vaping products.

We recommended above the Bill should stipulate that the DGH is responsible for implementing an independent system for testing nicotine levels of STPs on the market (funded by the tobacco industry). A similar system for testing other constituents should also be introduced. Such testing could be made the responsibility of the tobacco companies with the proviso that the DGH can at any time require independent testing of any constituent.

We strongly agree with the principle that STPs should only be sold if they are approved. However, we are concerned that describing STPs as 'approved' suggests the DGH views STPs positively, an impression tobacco companies could use as a marketing ploy. We suggest using alternative wording, such as 'permitted'.

We believe the proposed time period of 27 months for prohibition of STPs with non-approved constituents is too long and strongly recommend prohibition of non-compliant STPs should occur within 12 months.

We note the Bill does not make explicit any prohibitions regarding existing or new design features and innovations for STPs, and we believe this omission should be addressed.

We recognise that the regulatory powers included in Section 82B may be read as allowing the DGH to prohibit existing or future design features of STPs if 'constituents' are defined broadly. The current definition *"constituent means anything that makes up, is present in, or is emitted from a regulated product"* could include design features. However, if not stated clearly in the Bill, regulations introduced to prohibit design features may be challenged and held to fall outside the regulatory powers provided for in the Bill. We therefore believe that an explicit regulatory power for the DGH to prohibit design features should be included in the Bill.

Given the highly problematic nature of some current design features we believe there should be a review of current design features, including filters and filter capsules, and that regulations should be introduced within a specified time period to prohibit any design features identified as significantly increasing the addictiveness, palatability, appeal or harmfulness to health or the environment.

We can see no justification for introducing new STPs in Aotearoa; the only rationale for introducing new STPs is for tobacco companies to sustain or increase STP sales or their market share. The only exception should be for STPs that are likely to reduce damage to population health, with the onus on the tobacco industry to demonstrate that is the case. Therefore, we believe the Bill should freeze the STP market as has been recommended in the UK Khan Review. [8]

Recommendations

1. We recommend that in clause 82B(1)(a) the word 'safety' is removed so that the clause refers only to 'standards' for STPs.

2. We recommend that further detail/guidance should be provided about how the requirement to list constituents of products and their emissions will be implemented.
3. We recommend that the Bill requires that the DGH is responsible for implementing a testing system constituents of STPs carried out by the tobacco companies with provision for the DGH to require independent testing of any constituent.
4. We recommend a similar testing requirement and system should be put in place for all notifiable products including vaping products and non-combustible tobacco products.
5. We recommend a change in terminology from 'approved' to 'permitted' STPs to avoid any positive connotations that could be exploited to support the marketing of STPs.
6. We recommend that a specific regulatory power be added for the DGH to prohibit any specified current or future design features of STPs, such as filters and flavour capsules.
7. We further recommend that a clause is added requiring the DGH to review the design features of STPs and prohibit by a specified time period (we suggest within a year) any identified as significantly increasing the addictiveness, palatability, appeal or harmfulness to health or the environment.
8. We recommend adding a clause to prohibit the introduction of new design features, new products or new STP brands or brand variants to Aotearoa, unless specifically permitted by the DGH. Such approvals should be limited to STPs deemed very likely (with the burden of proof on the importers/manufacturers) to result in improved public health; for example, by virtue of being substantially less hazardous, addictive or appealing to people who smoke the current STPs.
9. We recommend that the time limit for prohibition of STPs with non-approved constituents or constituents at excessive should be reduced from 27 to 12 months.

Reducing the number of smoked tobacco product retailers

Comments

(i) Summary of Bill's provisions

The Bill empowers (Section 20M) the DGH to set a maximum number of approved smoked tobacco retailers (STR) using specified criteria and following consideration of population size and travel times, and after consulting with Māori. Anyone not approved as a STR will be prohibited from selling STPs and may be fined up to $400,000 if convicted of selling tobacco.

(ii) Rationale and evidence

Policy impact: We strongly support policy measures that reduce the number of tobacco retailers. The research evidence shows that reducing tobacco availability will decrease the risk of smoking experimentation and subsequent uptake among young people, and encourage people who smoke to quit smoking or switch to alternative non-STP nicotine products. The policy will also reduce the risk of impulse STP purchases and thus reduce relapse among people making quit attempts or who have quit smoking. Finally, the policy will send a clear signal that STPs are uniquely hazardous and addictive products that should not be sold as though they are normal consumer items.[40] We examine key outcomes below and consider two measures: density (a measure of how clustered tobacco stores are in a given area) and proximity (how easily people can access tobacco from a given location (typically their home)).

Young people: Recent reviews and meta-analyses have concluded that reducing tobacco retail outlet density decreases young people's risk of smoking experimentation; it thus follows that decreasing outlet density will help reduce young people's risk of smoking initiation.[41] For example, a meta-analysis found that greater retail density near young people's homes was associated with higher odds of recent (past month) smoking.[42]

> "Restricting access to tobacco outlets and controlling the number of outlets in residential areas may be an effective preventive strategy to help reduce adolescents' smoking" (p.27).
>
> **Source:** Finan LJ, Lipperman-Kreda S, Abadi M, Grube JW, Kaner E, Balassone A, et al. Tobacco outlet density and adolescents' cigarette smoking: a meta-analysis. Tobacco Control. 2019;28(1):27-33.

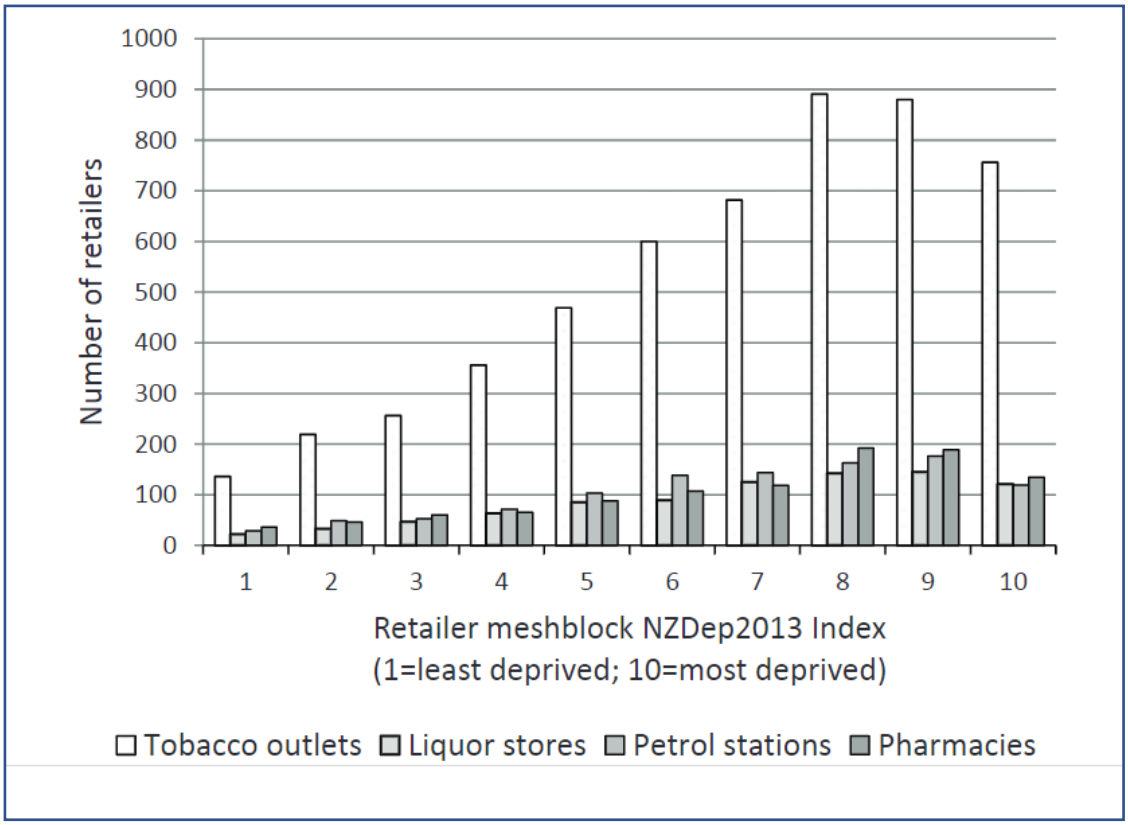
Evidence of associations between outlet proximity to young people's homes and smoking behaviours was more variable, likely reflecting young people's larger activity spaces, which typically extend well beyond their homes thus increasing exposure to outlets in other locations.[43]

Adults: Studies have found associations between tobacco outlet density and proximity, and adult smoking; this work has concluded that reduced density and decreased proximity could reduce tobacco use.[44-46] Earlier studies have found that, regardless of the density measure used, higher outlet density values were typically associated with higher smoking prevalence, greater tobacco use and smoking initiation (including greater smoking susceptibility and earlier age of first cigarette), and reported lower cessation outcomes (including fewer days smokefree in quit attempts).[47] Evidence of associations between outlet proximity and tobacco use patterns is more varied with some reviews not reporting associations[47] though specific studies have found that increases in the distance from home to a tobacco outlet was associated with an increase in the odds of quitting smoking.[45]

Equity impacts: Kong and Henriksen highlight the overabundance, and inequitable distribution, of tobacco retailers across communities.[48] New Zealand studies have documented similar inequities (see Figure 4 below).[49 50] One New Zealand study found that over half (53%) of all STRs and a mean of 5.7 were located within a kilometre of a secondary school.[49]

A recent mapping exercise confirmed this overabundance and inequities.[51] For example, Remuera has a total population of around 23,600 people; seven tobacco retailers and two specialist vape stores (SVRs) service this suburb (i.e., 3.0 tobacco retailers 0.8 SVRs per 10,000 people). By contrast, Manurewa has a total population of around 31,100 people; this suburb has 40 tobacco retailers and six SVRs (i.e., 12.8 tobacco retailers and 1.9 SVRs per 10,000 people). Please see Appendix 3 (p38) for an example of outlet mapping in relation to schools and neighbourhood deprivation level. This shows how many schools have ten or more SVRs and STRs within a kilometre radius, and this is particularly common for schools situated in more deprived communities.

Figure 4 Tobacco retail outlets, liquor stores, petrol stations and pharmacies by meshblock deprivation



Source: Marsh L, Doscher C, Cameron C, Robertson L, Petrović-van der Deen FS. How would the tobacco retail landscape change if tobacco was only sold through liquor stores, petrol stations or pharmacies? Australian and New Zealand Journal of Public Health. 2020;44(1):34-9.

Reductions in tobacco outlet density must also address inequities in tobacco availability.[50 52] Spatial modelling examining tobacco retailer proximity limits of 150m, 300m or 450m (i.e., restricting the distance between retailers) found these would reduce tobacco outlets by 35%, 49% and 58%, respectively.[53] However, this measure would not achieve the 95% reduction in outlets called for by the Māori Affairs Selection Committee.

Reducing the disproportionately high concentration of tobacco outlets in areas of higher neighbourhood deprivation is a pro-equity measure but more detailed work is required to assess how the policy will be implemented.[53 54] Decreasing retailer density increases the search and purchase costs of tobacco, including the time and distance travelled to the retail outlet; while this strategy is likely to encourage and support quitting, it may also have unintended outcomes.[55-57] A recent Scottish study estimated that limiting sales to supermarkets could reduce outlet numbers by 95% and have a positive equity impact; this work could form a basis for additional New Zealand analyses.[54] Yet, while supermarket-only sales reduced inequities, other approaches potentially increased inequities.[54]

Increased costs resulting from retailer reduction strategies could inequitably affect smokers who live in rural communities, including Māori, as increased spending on travel to purchase tobacco may fall more on these groups. Engagement with local iwi, as outlined in the Bill, will be critical to ensuring balances between benefits and potential risks are appropriately met. Although there is no evidence that smoking rates in rural areas are very different to those in urban areas, it is important to consider other factors, including equitable access to cessation support in rural settings.[58]

Relapse: Studies examining associations between outlet density or proximity, and smoking cessation and relapse, have reported mixed findings. One found increased risk of relapse among people living within 500m of a tobacco outlet; however reporting no association surmised that people who relapse likely live or socialise with others who smoke, and thus have domestic access to tobacco.[45 46]

Smoking and alcohol**:** The association between drinking alcohol and smoking tobacco is well established and some health risks associated with smoking increase multiplicatively when combined with heavy alcohol intake.[59] Alcohol use fosters smoking uptake and is associated with reduced quitting and increased relapse to smoking. [60] Social smoking tends to occur alongside alcohol consumption,[61 62] and established smokers smoke more while drinking and when at on-license premises when cigarettes are available for purchase.[63] People who smoke aged 18 to 34 years, a time when individuals begin socialising and consuming alcohol more frequently, make up nearly half of all adult smokers in New Zealand.[64] Disallowing the sale of tobacco in on-license premises would help break the link between drinking alcohol and smoking.[65 66] In addition, impulse tobacco purchases made from bars would decline, thus reducing relapse to smoking, which often occurs along with alcohol use.[67 68]

A recent New Zealand survey of on-licence premises (N=1114) found that 6.5% sold tobacco (17.4% of hotels; 17.5% of taverns, and 1.6% of restaurants). On-licenses were more likely to rate tobacco as "unimportant" (51.7%) to their business than "important" (30.0%), although premises where the closest tobacco retailer was at least 1 km away were associated with a higher score. Similar proportions of businesses selling tobacco were opposed to (45.7%) and supported (47.2%) the policy of removing all tobacco sales from on-licence premises.[69] Given the low proportion of outlets selling tobacco and the overall low importance of tobacco sales, disallowing tobacco sales in on-licence premises seems unlikely to represent a substantial loss of revenue for outlet owners and would disrupt the smoking and alcohol use pairing noted above.

Modelling data: Modelling studies demonstrate that, while denicotinisation will have the greatest impact on smoking prevalence, retailer reduction will also have a significant impact, particularly in the first year following the policy introduction (see Figure 3, p5).

Policy implementation: We note that modelling studies indicate the reduction in retail outlets needs to be very large (at least 90%) to most effectively reduce smoking prevalence.[70] The Bill does not currently specify either a maximum number of outlets permitted or a percentage reduction that will be applied to existing outlet numbers. We recommend the Bill sets a **maximum number** of STRs to greatly reduce the retail availability of STPs and density of tobacco retail outlets. Setting a percentage of existing retailers leaves the denominator open to manipulation, given New Zealand does not have a retailer register. We believe the Bill should set out details of how the process to assess outlets wishing to sell tobacco will work, particularly the criteria that will be set and applied, and the renewal process. We strongly suggest that the retailer reduction measure is sequenced to occur after mandated denicotinisation (see p17-18).

We strongly support introducing criteria that retailers must satisfy before they can become a permitted STR (clause 20I), including requirements to meet security and training standards (20I (d)). Section 82A sets out further possible criteria for consideration when allocating permits to sell STPs, including fit and proper person criteria and requirements for business systems.

We suggest the Bill specifies a time period for permits and criteria for permit renewal. Criteria could include requiring retailers to provide information about smoking cessation support, and supply the Ministry of Health with six-monthly STP sales data to assist with monitoring and evaluating the Smokefree Aotearoa 2025 Action Plan measures. Retailers who do not meet these criteria, or who receive infringement notices (or are prosecuted) for making sales of STPs to minors, would not be eligible to have their permits renewed. We also suggest adding an overarching statement about the intended goals/guiding principles of the STR assessment process.

We note that clause 20H allows for retailers to sell STPs through internet sites and via app-based sale and delivery processes. Many internet sites lack effective age verification procedures, and age restrictions are very hard to apply, creating a high risk that age restrictions would not be applied as intended, and that both the number of sales sites and volume of online tobacco sales would increase. These outcomes would greatly undermine the Bill's aim of reducing the availability of STPs. We therefore strongly recommend that no internet sales of STPs are permitted to prevent this platform from being exploited to undermine measures restricting STR numbers.

Flexibility to allow access to STPs through internet sales is possible; for example, through temporary measures introduced through the Epidemic Management Act during periods of lockdown.

Addressing concerns about the retailer reduction policy: We note that tobacco companies, retailers' associations that have tobacco companies as members (e.g., New Zealand Association of Convenience Stores), and some retailers, have argued that a retailer reduction strategy would threaten the viability of their business. They argue that tobacco generates footfall and that people who visit an outlet to purchase tobacco (a product with a low profit margin) also purchase higher margin products while in-store, thus contributing to overall store profitability. Researchers in New Zealand, the US and UK have tested this argument and concluded that tobacco does not account for a high proportion of sales or generate significant additional revenue for stores.[71-73]

A New Zealand consumer intercept study found that only around 14% of sales involved tobacco and only a third of those (5% in total) involved tobacco and another item.[72] Scottish research analysing UK point of sale data from 2016 to 2019 examined the importance of tobacco to store footfall and found the number of transactions involving tobacco had declined by nearly half, and to a greater extent than any other product regarded as generating footfall.[73]

Recommendations

1. We recommend stipulating that the maximum number of retailers allowed must substantially reduce the retail availability of STPs (aligned with the new purpose we have suggested in appendix 1, p34) and specify a maximum number of permitted outlets (e.g., no more than 300 STRs, with a process developed to reduce numbers further).
2. We recommend outlining the guiding principles of the STR application granting process. For example, criteria could ensure the distribution of STRs is secure, takes cognisance of potential unintended impacts, enables reasonable supply in remote locations, and supports public health goals, such as minimising availability to minors and preventing concentrations of STRs in higher deprivation neighbourhoods.
3. We recommend specifying the requirements that STRs must meet before their application is granted, to ensure retail availability is consistent with the Bill's wider purposes of decreasing youth smoking uptake, supporting cessation, and reducing relapse. Compliance should be monitored and reviewed to inform future reapplications. Requirements could include:
    - Making information about smoking cessation (e.g., the Quitline) and local smoking cessation support services available to all people purchasing tobacco;
    - Providing the Ministry of Health with STP sales data to assist with monitoring and evaluation, and any additional planning for Smokefree Aotearoa 2025;
    - No history of successful prosecutions or infringement notices for underage sales of STPs or other regulated products;
    - A track record of compliance with all requirements of STR status (reapplication criterion).
4. We recommend that on-licence premises are not granted permits to operate as STRs, to help break the link between smoking and drinking.
5. We recommend adding a clause that STRs receive sales permits for a fixed period (e.g., no more than two years) and require renewal of their permits, including a re-assessment of whether they continue to meet the relevant criteria, at the end of that period.

6. We recommend disallowing STP sales via internet sites.
7. We recommend commencing the STR permit process and reducing STR numbers after denicotinisation has been in place for six months to accelerate declines in STP sales. We also recommend adding a date by which the retailer reduction process should have been completed e.g., one year after the introduction of mandated denicotinised tobacco.

Introducing a smokefree generation policy (SFG)

Comments

(i) Summary of Bill's provisions:

Sections 40A and 40B of the Bill provide for the creation of an SFG by specifying that smoked tobacco products must not be sold, delivered or supplied to anyone born on or after 01 January, 2009. The Bill sets out penalties for breaches of these Sections.

(ii) Rationale and evidence

Policy rationale: We strongly support the introduction of the SFG policy, which is a proportionate response to managing a highly dangerous product that kills its users when consumed exactly as intended. Denicotinisation and reducing the availability of tobacco products will catalyse declines in smoking prevalence; the SFG will sustain reductions in smoking prevalence by preventing recruitment of 'replacement smokers' (a term tobacco companies have used to refer to young people), on whom tobacco companies' profitability depends.[74] Further, the SFG recognises young people's right to protection from a uniquely harmful product and addresses historical anomalies that have allowed a highly addictive product like tobacco to be sold as though it were a normal consumer product.[75] The SFG will protect rangatahi from the burden of smoking and help them retain the freedom that addiction removes.

Responding to regret: The Bill recognises the enormous harm tobacco products cause, including the premature death of two thirds of people who smoke long-term.[76] The vast majority of these people regret having started smoking, wish to quit, and make frequent quit attempts.[77]

Data from the NZ International Tobacco Control survey conducted in 2018 found that 82% of participants reported they regretted starting to smoke.[31] Virtually all (99%) believed that smoking is addictive and agreed that they personally were addicted (93%).[78] Almost three quarters (71%) planned to quit, with over a third (36%) intending to quit in the next six months. A large majority (84%) had tried to quit previously, with almost half (46%) trying to quit in the last year. These findings were similar between Māori and non-Māori participants (e.g., 45% Māori vs 52% non-Māori had tried to quit in last year, 34% Māori vs 37% non-Māori were planning to quit in the next six months).

The SFG measure outlined in the Bill responds to this evidence by setting out age-appropriate restrictions, in the same way that governments regulate other risky activities, such as drink driving.

Need for an SFG policy: The SFG offers several important advantages over increasing the minimum age for sale of STPs. First, it makes it clear that there is never a safe age at which tobacco use may start and removes "rite of passage" connotations developed and fostered tobacco companies to position smoking as a sign of maturity.[75] Second, the SFG recognises that tobacco is not a normal consumer product but a toxic and addictive substance from which young people deserve protection. The SFG policy thus draws on consumer protection measures applied to numerous other products and recognises the threat to safety and well-being that tobacco poses. Finally, and more fundamentally, age restrictions may only delay the emergence of 'replacement smokers' rather than close the pipeline altogether; the SFG policy will provide more comprehensive and sustained protection.

***Policy impact*:** Evidence of the SFG's impact comes from several sources. First, increased age restriction policies that have raised the age for legal sale or purchase of STPs to 21 years provide important insights into the SFG's feasibility and likely effects. In late 2019, the US introduced a "tobacco 21" (T21) policy. This amendment to the Federal Food, Drug, and Cosmetic Act raised the federal minimum age for sale of tobacco products from 18 to 21 years, making it illegal for any retailer to sell any tobacco product, including e-cigarettes, to anyone aged under 21 years.

Analyses of the T21 policy's impact indicates that age restrictions are effective; they reduce use of multiple tobacco products, particularly among younger adolescents[79] and accelerate declines in smoking prevalence[80 81] Comparisons of smoking prevalence among young people in jurisdictions with and without a T21 policy report lower likelihoods of smoking among young people protected by T21 provisions;[82 83] retailer compliance with the new policy also increased.[84] In summary, the T21 measure appears to have been effectively implemented with strong reductions in tobacco product purchases and use among young people. These findings give high confidence that the SFG measure will have similarly beneficial effects.

Modelling studies lend further support to the SFG's likely impact. These have estimated the SFG policy could halve smoking prevalence within 14 years among people aged 45 and younger, and achieve a more than five-fold health gain to Māori, compared to non-Māori.[70] As Figure 3 (page 5) illustrates, while denicotinisation will have the greatest impact on reducing inequities caused by smoking, the SFG will also reduce disparities in smoking prevalence and the health inequities that follow.

The New Zealand International Tobacco Control (NZ ITC) survey of around 1000 people who smoke or recently quit found more than three quarters (78%) supported the SFG; support for the SFG was around ten percent higher than support for increasing the legal purchase age for tobacco from 18 to 21.[85] Support among the general population is likely to be higher still, making the SFG an overwhelmingly popular policy.

A recent in-depth study with young people aged 17 and 18 asked them to imagine the SFG was coming into effect in 2022 and applied to those aged 17 but not to those aged 18. A large majority of participants, which included people who smoked and did not smoke, supported the SFG. They saw the policy as liberating rather than restricting, and prioritised a longer term perspective that considered the "bigger picture" lying beyond their own interests.

> *I don't really think that's a really important freedom at all, because I mean, okay, it is important, but banning, I feel like banning smoking has many more benefits, rather than saying, "Oh, it's freedom, so we should have it, we should keep it."*
>
> *The government essentially is supposed to keep you safe, and they're not supposed to… make things readily available that are gonna actively harm you.*
>
> *…it [the SFG] would just change the world in a few years. Like, if you stop… the young, the next generation will stop. Then when they're the leaders of their generation, or generations below them… it just will get better and better and better, the younger they go.*
>
> **Source:** Hoek J, Lee E, Teddy L, Fenton E, Ball J, Edwards R. Under review.

Policy implementation: We welcome the SFG application to the sale or supply of STPs and not to its purchase or use. This important distinction removes the risk of criminalising young people who use STPs. We acknowledge concerns regarding possible criminalisation of people, such as parents or older siblings, cousins and friends, for small scale social supply of STPs; we believe the Bill should

differentiate between corporate commercial supply of STPs and small-scale non-commercial supply, and the latter should be classified not as an offence but as an infringement. Furthermore, we believe there should be a clear expectation of 'light touch' enforcement for small-scale non-commercial supply, as has been applied with other recent legislation, such as the Smoke-free Environments (Prohibiting Smoking in Motor Vehicles Carrying Children) Amendment Act 2020, where social marketing campaigns and an educative approach were used prior to applying infringement penalties. We do not believe it is appropriate that people engaging in minor non-commercial social supply transgressions could be at risk of prosecution.

Addressing concerns the Smokefree Generation: Debate over the SFG has featured several erroneous arguments that often rely on incomplete data and/or questionable logic or interpretations of evidence.

'We have ended youth smoking': While youth smoking has declined to historically low levels,[86] stark inequities persist. For example, 9.3% of Māori students reported regular (i.e., at least monthly) smoking in the 2021 Snapshot Survey conducted by ASH NZ (cf. 2.7% of NZ European students).[87] We do not believe we can regard youth smoking as unproblematic and unworthy of attention while inequities such as these continue.

Surveys of the general population show reduced smoking prevalence among 14 to 15 year olds is **not sustained** among older age groups and the flow of 'replacement smokers' continues. The most recent NZ Health Survey shows current (i.e., at least monthly) smoking prevalence among 18 to 24 year olds was 11.8%, a figure that contradicts claims the Smokefree 2025 goal has already been achieved.[88] Smoking among 18 to 24 year olds is a key indicator of the replacement smoker pipeline (data from 14 to 15 year olds are less helpful in this respect) and current population data do not support claims that reduced youth smoking means smoking among young adults no longer merits attention.[89]

More detailed analyses of the 2019/2020 NZ Health Survey data reveal that smoking prevalence is more than twice as high among Māori than among non-Māori. Specifically, overall smoking prevalence among young people aged 15-24 was (12.4%), but among Māori it was **26.4%**, and among non-Māori, 9.0%.[90]

The finding that around one in ten young people and one in four Māori rangatahi are still taking up smoking and face potential lifelong addiction and premature death is an indictment of the failure to protect the next generation from STPs, particularly as it is now 60 years or more since they were first shown to be so deadly.

These figures emphasise smoking among young people remains highly problematic and imposes a particularly severe and on-going burden on young Māori, and suggests the SFG is a timely, appropriate and much-needed measure to minimise smoking uptake among young people and help ensure rangatahi Māori enjoy the same health and well-being as non-Māori.

Informed choice myth: Tobacco companies have long argued that smoking is an "informed adult choice".[91] Our research has found few people who smoke made anything approximating an informed choice to embark on a lifelong addiction. Nicotine dependence typically begins when young people casually experiment with smoking, often under the influence of alcohol or peer pressure. What began as a social practice often evolves rapidly and many young people find they have become dependent on a product engineered to ensure rapid addiction. Once addicted, most people make numerous attempts to quit but many cannot overcome their nicotine dependence. Virtually no-one who experiments with smoking fully comprehends what living with addiction would be like, adequately appreciates the risks of life-long smoking, appropriately applies these risks to themselves, and then accepts them. [92] "Informed choice" is a tobacco-industry myth designed to relocate blame for smoking's harms to people who smoke. The SFG recognises informed choice is a misnomer and that nobody can willingly embark on a lifelong addiction before they understand and accept the burden this will place on them and their whānau, and the price it will extract.

Increased age restrictions will suffice: Findings from the successful T21 policy introduction[81 82 84] may appear to question why the Bill proposes an SFG approach rather than increased age restrictions. There are several reasons why an SFG proposal offers important benefits over increased age restrictions. First, the SFG recognises smoking poses a sustained threat to young people and, appropriately, treats tobacco as a product that harms consumer safety and well-being. It addresses the historical anomaly, and the many years of tobacco industry deception, that allowed tobacco to be introduced and sold as a consumer product. Second, age-restriction policies do not provide comprehensive protection and have the disadvantage that, as each year passes, some young people "graduate" beyond the age limit.

"Leakage" will render the policy ineffective: The SFG deliberately focuses on the longer-term; denicotinisation and reduced retail availability will greatly reduce the appeal of tobacco and opportunities for "social" supply to occur. While some social supply may occur as the policy becomes embedded, over time, the social distance between people who may legally purchase tobacco and those protected by the SFG will grow, thus reducing social supply opportunities.[93]

(iii) Drafting error

We note a drafting error in the Bill that will have significant implications. We understand that the error has been recognised, but have recorded it here to ensure it is corrected. The drafting error means that the existing ban on sale of STPs to people under 18 will discontinue on Royal Assent if the Bill is not amended and will not be reinstated until 2027.

The error occurs because clause 19 amends section 40 so that the ban on sale to under 18s applies only to Notifiable Products (e.g., vaping products) but not Regulated Products (e.g., STPs). Clause 2 of the Bill, which refers to the Bill's commencement dates, states that sections 19(1) and 19(3) will come into force on 1 Jan 2027; however, 19(2), which refers to the ban set out in 40(1) on sale of a regulated product to an under 19, is to come into force on Royal Assent. The effect of the amendment in clause 19(2) is to change Regulated Products to Notifiable Products; as this change comes into effect on Royal Assent, the ban on sale will only apply to notifiable products only.

Recommendations:

1. We recommend introducing the SFG after denicotinisation and substantial retailer reduction have been implemented and consider bringing forward the implementation date. Once denicotinisation has been introduced and STPs' availability has been greatly reduced, smoking prevalence and uptake among young people will have been minimised, thus enabling earlier implementation of the SFG policy (i.e., prior to 2027) to be considered.
2. We recommend that the Bill include regulatory powers enabling the introduction of a 'nicotine-free generation' policy. This would end the sale of STPs, and all notifiable products including vaping products and non-combusted tobacco products, to all people born on or after a specified date.. We recommend that further consideration be given to introducing an NFG as part of the comprehensive review of vaping legislation and regulations we have recommended on p10 of our submission. We recommend including an exception to allow vaping products to be used as an aid to stopping smoking by a anyone born on or after the specified date who smokes.
3. We recommend that the definition of supply of STPs in the Bill should differentiate between supply by corporate entities and supply by persons such as individual's friends and family.
4. We recommend that the provision prohibiting supply by a corporate entity should omit the reference to in a public place, as commercial supply of STPs should be considered an offence wherever it occurs. We recommend the penalty for supply by corporate entities should be the same as the penalties for sale, i.e., $150,000.
5. With reference to supply by 'a person', we suggest keeping the reference to 'in a public place'. However, recommend that this offence should be specified as an infringement offence, with

section 87 (see cl 47), amended accordingly, which would involve a lower penalty. Refer to the proposed amendment to section 87 (see cl 47) where the max fee of $500 is specified.

6. We note in the section 'Offence Provisions' (p31) that the phrase 'knowingly or recklessly' should be omitted and supply of STPs offences treated as strict liability with defence.
7. How the drafting error we have identified is addressed is up to drafters. It perhaps could be rectified simply by changing the commencement provisions. We recommend that it may however be clearer for everyone if the ban on sale of regulated/notified products to under 18s is split in two:
    - One set of provisions to continue the ban on sale of Regulated Products to under 18s until SFG comes in (to be repealed when SFG provisions have effect)
    - One set of provisions to ban sale of Notifiable Products to under 18s.

Imposition of levies

Comments

Section 44 modifies the regulations for the imposition of levies and specifies that these can be applied to retailers, distributors, importers or manufacturers of STPs and notifiable products. We welcome the inclusion of powers to require a levy by these businesses. However, we are not aware of these powers having been used or of any stated intent to do so. We note that the UK Khan Review recommended introducing a levy on tobacco industry profits from cigarette sales to pay for measures supporting their 2030 Smokefree Goal. [8] We believe a similar approach should be implemented in Aotearoa with funds used to support implementation of the major legislative measures included in this Bill and additional interventions included in the Smokefree Aotearoa 2025 Action Plan, including enhanced smoking cessation support and mass media campaigns, and costs of environmental clean-up of tobacco product waste, including cigarette filters.

Recommendation

1. We recommend adding a power for the DGH to impose levies on retailers, distributors, importers or manufacturers of STPs and notifiable products, with revenue used to fund any additional costs of implementation and enforcement of the measures included in the Bill and the Smokefree Aotearoa 2025 Action Plan and considered to cover externalities imposed by STPs such as the costs of environmental clean-ups and waste processing.

Record-keeping

Comments

We welcome the new requirement for manufacturers, importers, exporters, distributors, or retailers of regulated products to keep accurate records (for three years) of regulated products that they manufacture, import, export, buy, sell, or supply; and for manufacturers to record constituents used in the manufacture of each regulated product. However, we believe that to ensure this information is useful in monitoring and evaluation, supporting systems and infrastructure must be established to collate, analyse and report on the data .

Recommendation

1. We recommend establishing a system to ensure that information is collated on the manufacture, importation, sales and constituents of regulated products and reported on annually, and made available to assist research into the STP and vaping product markets in Aotearoa.

Specialist vape retailers

Comments

Part 1B Sections 20P-20R, and 25 stipulate that the DGH is responsible for approving specialist vape retailers (SVRs). There is currently no limit set on the number of SVRs. The criteria for approving SVRs set out in the 2020 Act stipulate that outlets are fixed permanent structures and that a minimum proportion of total sales from the retail premises must be from vaping products. The Bill now stipulates that SVRs should also be '*appropriate premises from which to operate a stand-alone business*'.

It seems likely that this additional wording is a response to reports from enforcement officers (which we have also received) that dairy owners are frequently setting up specialist vaping retail outlets by sectioning off parts of their premises and claiming this practice complies with the current rules. These changes seem likely to have caused a substantial expansion in the number of SVRs ,and hence the number of retailers selling a full range of flavours. Furthermore, these activities appear to undermine the stipulation that SVRs are R18 only premises.

This apparent increase in the retail availability of vaping products that appeal to young people is particularly concerning given the rapidly increasing vaping prevalence among young people. For example, the NZHS reported that daily vaping prevalence increased from 2018/19 to 2020/21 from 1.7% to 5.8% among 15-17 year olds, and from 5% to 15.3% among 18-24 year olds.[94] It is also possible that 'SVRs' situated in dairies are less likely to comply with age of sale restrictions further increasing youth access to vaping products.

The additional wording in the Bill is extremely vague and seems unlikely to address this issue, as dairy owners may argue their premises are 'appropriate' (or mount a challenge if their premises are deemed not to be appropriate) and claim that the vaping side of their business is 'stand-alone'.

Part of the rationale for making a full range of vaping products available in SVRs is presumably to enable staff with appropriate training and expertise to offer advice and support that assists people using STPs to switch to vaping products. However, current SVR requirements do not specify that staff have any basic training in smoking cessation, knowledge of where smoking cessation support is available, or requirement to provide information about local cessation services or the Quitline. We believe the Bill offers an opportunity to address these omissions.

Recommendations

1. We recommend that the criteria for approval as a SVR should be tightened to ensure that SVRs have as their primary purpose selling alternative products to STPs that can aid people who smoke to switch to a reduced harm product.
2. We recommend adding specific criteria to ensure SVRs fulfil this purpose. For example, requiring SVRs to have information available about local smoking cessation services and the national Quitline, and specifying that SVR staff have training in delivering brief smoking cessation interventions and making referrals to cessation services.
3. We recommend that the outcome of SVR regulation is monitored by identifying and recording where SVRs are located, developing a programme of test purchasing and robust enforcement, and undertaking regular surveys of young people about the source of vaping products. The regulations should be kept under review and further restrictions introduced if necessary (e.g.,in response to community concerns about vaping among rangatahi or excessive concentrations of SVRs in particular locations).

Offence provisions

Comments

We have some concerns about how some offences are categorised and constituted. This will likely affect the feasibility of successful prosecution where offences are committed.

The Bill has different provisions with two different approaches as to what constitutes an offence, and what is required to establish that an offence has occurred, either:

1. An offence is committed when (a) an act or omission takes place in contravention of a specified duty/obligation and (b) no fault must be proved ('strict liability'); or whether,
2. For an offence to be committed in addition to the act/omission, a degree of fault must be involved – the act or omission must be proved by the enforcement agency to have been done 'knowingly or recklessly' by the person charged.

Inclusion of the words 'knowingly' or 'recklessly' means that the enforcement agency must prove fault i.e. that the person charged knows the relevant act or omission is non-compliant. This may be very difficult to establish. Including the words 'knowingly' or 'recklessly' is therefore likely to make compliance with the duties and obligations specified in the Bill less enforceable. While proving a 'mental element' is morally right for offences such as murder, proving a mental state of mind has long been recognised as often inappropriate and unnecessary for the administration of government functions e.g., traffic offences and tax liability; and hence a strict liability approach is usually taken. It is usual (though not always the case) for strict liability offences to be combined with a statutorily specified defence, e.g., 'without reasonable excuse'. This approach recognises the need for prosecution fairness, with defences available to be proved by the person alleged to have committed the offence ('reverse onus').

While there are advantages and disadvantages to each approach, the strict liability approach is clearly more straightforward to implement and remains fair to an alleged offender, given the availability of a statutory defence.

Additional issues concern whether an offence is labelled as an 'infringement offence'. This is generally associated with the strict liability approach which is discussed in the section on the SFG (p27-29) in relation to the non-commercial social supply of STPs to underage people by friends and whānau. The Bill has a far greater use than in the current Act of fault (i.e., through the use of 'knowingly or recklessly') as an element of offence provisions. When strict liability is used, the defence provisions are less detailed than in the current Act. It is often not clear why for some offences fault is required and for others not.

We consider that the greater use of 'fault' provisions in the Bill is inappropriate, unnecessary, and will make the Bill less enforceable; and instead recommend wider use of the 'strict liability' provision.

Recommendations

1. We recommend that almost all offences in the Bill, with a few exceptions:
    - be constituted on occurrence of an act or omission on noncompliance with the relevant duty or obligation; and
    - A 'strict liability' approach in which proof of liability and hence appropriate conviction occurs if the act or omission is proved; but
    - with a defence also specified: i.e., 'without reasonable excuse' or similar formula where appropriate.

2. We have set out our recommendations for specific offence provisions in Appendix 4 (p39).

Monitoring, evaluation and review

Comments

Detailed monitoring and robust evaluation of the Smokefree Aotearoa 2025 Action Plan and key measures included in the Bill will be required to inform the implementation process. Moreover, this information will be vital to rapidly detecting and responding to any unintended adverse impacts, such as growth in the illicit STP market. Finally, monitoring is vital to generating evidence about the effectiveness of the measures introduced. The Action Plan includes a commitment to undertaking thorough monitoring and evaluation. However, policy implementation in Aotearoa is often not accompanied by a proactively planned or systematic evaluation; as a result, major policy interventions and innovations may occur without adequate (or any) evidence of their impact.

We suggest that the Bill include specific clauses requiring high quality and comprehensive monitoring and evaluation, including annual reports on progress.

Given the critical importance of ending the smoking epidemic in Aotearoa (for health, health equity, and economic reasons), we suggest the Select Committee consider whether the legislation should also contain additional mechanisms that could be triggered for implementation if monitoring and evaluation indicate further measures are necessary in order to reach the Smokefree Aotearoa 2025 goal for all peoples. Additional measures could include:

- A sinking lid intervention that mandates an ongoing absolute reduction in STP imports/products released to the market every six month period, until zero supply is achieved over 3-5 years (supporting literature on the sinking lid intervention available on request).
- Implementing additional restrictions on the retail availability of tobacco products, such as limiting STP sales to fewer outlets (i.e. fewer than achieved through the current legislation) that are government owned or mandated (e.g., selected pharmacies).

Recommendations

1. We recommend that, as set out in the Smokefree Aotearoa 2025 Action Plan, comprehensive monitoring and surveillance mechanisms for progress towards Smokefree Aotearoa 2025 are rapidly established. To support enhanced monitoring, we recommend that the enforcement capacity and capability of the smokefree enforcement workforce be reviewed and strengthened as necessary.
2. We recommend that the following clauses and requirements relating to monitoring, evaluation and reporting are added to the Bill.
    a. Requires the DGH to set targets relating to regular and daily smoking rates across all population groups for the years 2023, 2024 and 2025 and beyond; and
    b. Requires the DGH to set targets relating to regular and daily use of HTPs and e-cigarettes/vaping among people aged under 25 years across all population groups for the years 2023, 2024 and 2025 and beyond;
    c. Requires the DGH to set a target for the implementation of mandated **denicotinisation** of all smoked tobacco products and reduction in STRs below the specified maximum (500 retailers).
    d. Requires publication of annual reports relating to these targets, including:
        I. Current and daily smoking rates across all population groups from 2023 and beyond; and
        II. Progress in implementation of denicotinisation of smoked tobacco products and reduction in retailer numbers from 2023; and

III. Prevalence of regular and daily use of heated tobacco products, vaping and non-combusted nicotine products among people under 25 years for the years 2023, and beyond.

3. We recommend that the DGH must report by the end of 2025 whether additional measures to improve compliance with the purposes and achievement of the targets specified in the Bill are necessary or desirable.

Appendices

Appendix 1: Suggested purposes for the Bill

We believe that it is important for the Bill's purposes to be articulated in a coherent manner. This will help readers have a common understanding about what the Bill is aiming to achieve and provide key outcomes that will help ensure this happens. This will also provide a basis for evaluation of the Bill, and a rationale and justification for enforcement.

As noted under "Purposes of the Bill", we are concerned that the purposes of the Bill do not include over-arching purposes and appear to give less priority to vaping, smokeless tobacco, and heated tobacco products than the existing statute, and in particular fail to explicitly state the requirement to protect rangatahi from taking up vaping. The Bill does this by a significant change to section 3A (as given effect by clause 5); and by removal of section 49 with no replacement (see clause 27).

We have accordingly suggested that aspects of such provisions as outlined in the current Act be reinstated in the Bill. We recommend the following:

The purposes of this Act are:

1. To reduce daily smoking rates to less than 5% for all population groups (in particular, Māori and Pasifika) to achieve the Smokefree Aotearoa 2025 goal, or as soon after this year as possible, by provisions that:
    a. Prevent all young people today and successive generations from ever using smoked tobacco products;
    b. Reduce disparities in smoking rates and smoking-related illnesses between New Zealand population groups, and in particular between Māori and other groups;
    c. Prevent the harmful effect of other people's smoking on the health of others, and especially on young people and children;
    d. Minimise the appeal and addictiveness of smoked tobacco products by only allowing the sale of denicotinised smoked tobacco products;
    e. Substantially reduce the retail availability of smoked tobacco products;
    f. Eliminate all forms of advertising and promotion of smoked tobacco products;
    g. Ensure key population groups (particularly Māori) are engaged as part of developing, implementing and evaluating the Act's key measures;
    h. Give effect to certain obligations and commitments that New Zealand has as a party to the WHO Framework Convention on Tobacco Control, done at Geneva on 21 May 2003.
2. To regulate notifiable products (including vaping products and smokeless tobacco products), by provisions that:
    a. Discourage people who do not smoke (particularly young people) from ever taking up notifiable products;
    b. Support people who smoke to switch to regulated products that are significantly less harmful than smoking;
    c. Encourage people to stop using notifiable products;
    d. Discourage people who have stopped smoking or using notifiable products using regulated products from resuming smoking or using notifiable products;
    e. Monitor and regulate the presence of harmful constituents found in notifiable products and their emissions;
    f. Regulate the retail availability of notifiable products;
    g. Regulate and control all forms of marketing, including the advertising and promotion and availability of notifiable products.

Appendix 2: Evidence on illicit tobacco trade in Aotearoa

Introduction

This paper provides evidence on the extent of and trends in the illicit tobacco market in Aotearoa. We also compare illicit tobacco to other illicit markets that governments have to manage.

While any illicit trade in tobacco is unwanted in Aotearoa, we need to place this problem in context and remember that around 5,000 citizens die from tobacco-related causes every year. Recent evidence for smuggled manufactured cigarettes suggests this illicit market is around 5% of the total market for STPs. It seems especially to involve smuggling from China and South Korea and the illicit sales appear higher in some Auckland suburbs. This evidence means that focused efforts on imports from these countries and in Auckland may offer improved control of illicit activity.

Furthermore, although denicotinisation of tobacco may result in a temporary increase in the illicit tobacco market, we think it crucial to remember that the new law will most likely rapidly drive down the demand for **all** tobacco products, including, ultimately the illicit market. A possible outcome is that the illicit market may increase relatively as a proportion of the STP market, but may decrease in size in absolute terms because the overall STP market size has shrunk.

What is the size of the illicit market in Aotearoa?

Table A1 summarises studies of this market. The table excludes tobacco-industry funded reports given the competing interests involved. The most recent study indicates the size of the illicit market for manufactured cigarettes is around 5% of the total market (see last row in Table A1). [95]

What might happen to the illicit market with denicotinisation?

It is plausible that the law requiring denicotinisation of tobacco may result in a temporary increase in the illicit tobacco market among people who decide not to quit and who do not switch completely to vaping. Nevertheless, the evidence from randomised trials using denicotinised tobacco and modelling studies suggests that denicotinisation will very substantially drive down smoking prevalence and demand for smoking (see p15). As such, the legal and illicit market sizes are ultimately likely to greatly decline in size.

Furthermore, even if the price of illicit tobacco is 50% of the current legal price, this price would still typically be more than the cost of vaping in Aotearoa (to obtain the same dose of daily nicotine), so for many people who smoke who cannot or do not wish to quit using nicotine products, vaping will continue to be a more appealing alternative in terms of cost, even if illicit market cigarettes and tobacco are available.

Customs expenditure on enforcement will also help determine the future market size. If this is increased and effective and targeted measures are employed (e.g., imports from China attract greater surveillance and more “drug dogs” are trained to detect tobacco in imported containers), the success rate of enforcement measures would likely increase – further depressing the size of the illicit market.

Table A1 Summary of previous studies/reports of relevance to the size of the illicit tobacco market in Aotearoa

Year(s) of data collection	Summary: details of findings and commentary
2008/2009	Littered tobacco packs were collected in four cities and six New Zealand towns/rural locations between November 2008 and January 2009 by university researchers. [96] The study reported that 3.2% of packs were foreign (42/1,310).
2012/2013	Littered tobacco packs were collected from seven locations across New Zealand by university researchers. [97] This study was undertaken between November 2012 and January 2013. The majority of packs were collected in the Christchurch, Wellington and Nelson/Marlborough regions. [97] Of these, 5.8% were foreign (103/1,776). NB This, and the earlier study, may have been over-estimates given some foreign packs will have been discarded by tourists and because no adjustment was made for Australian packs that can be legally sold in the country.
2013	A study by researchers with the non-governmental organisation "ASH", [98] considered data on the import and seizure of legal and illegal tobacco from New Zealand Customs. It also examined previous literature and annual tobacco returns figures. It estimated that illicit products made up 1.8-3.8% of the New Zealand tobacco market.
2021-2022	A nationwide study of littered tobacco packs between May 2021 and April 2022 found a total of 1,590 packs. [95] [NOTE-THIS REF NEEDS TO BE CHANGED TO "IN PRESS" IN TOBACCO CONTROL] Of these packs, 36 were foreign (2.3%) (the study excluded Australian packs that can be legally sold in New Zealand). The two major source countries were China (n=25; 1.6%) and South Korea (n=9; 0.6%). The distribution of foreign and potentially smuggled packs was dominated by Auckland (6 suburbs/CBD), and Wellington (6 suburbs/CBD). When the analysis was adjusted by population distribution, the estimated national prevalence of foreign packs was 5.4% (95% confidence interval: 4.4% to 6.6%). The study reported that: "*The evidence that smuggled packs are concentrated in certain cities could allow for more targeted enforcement (e.g., of illegal retailing by stores in Auckland as reported in the media [99] [100]). Similarly, the small number of source countries identified may allow for Customs to further target imported cargo from these jurisdictions.*" NB This study has the particular advantage of being conducted during Covid-related travel restrictions. This meant that all foreign packs could be assumed to be smuggled packs and not from tourists (e.g., smuggled via shipping to New Zealand which continued without significant disruption during the Covid pandemic).

Putting the tobacco illicit market into context

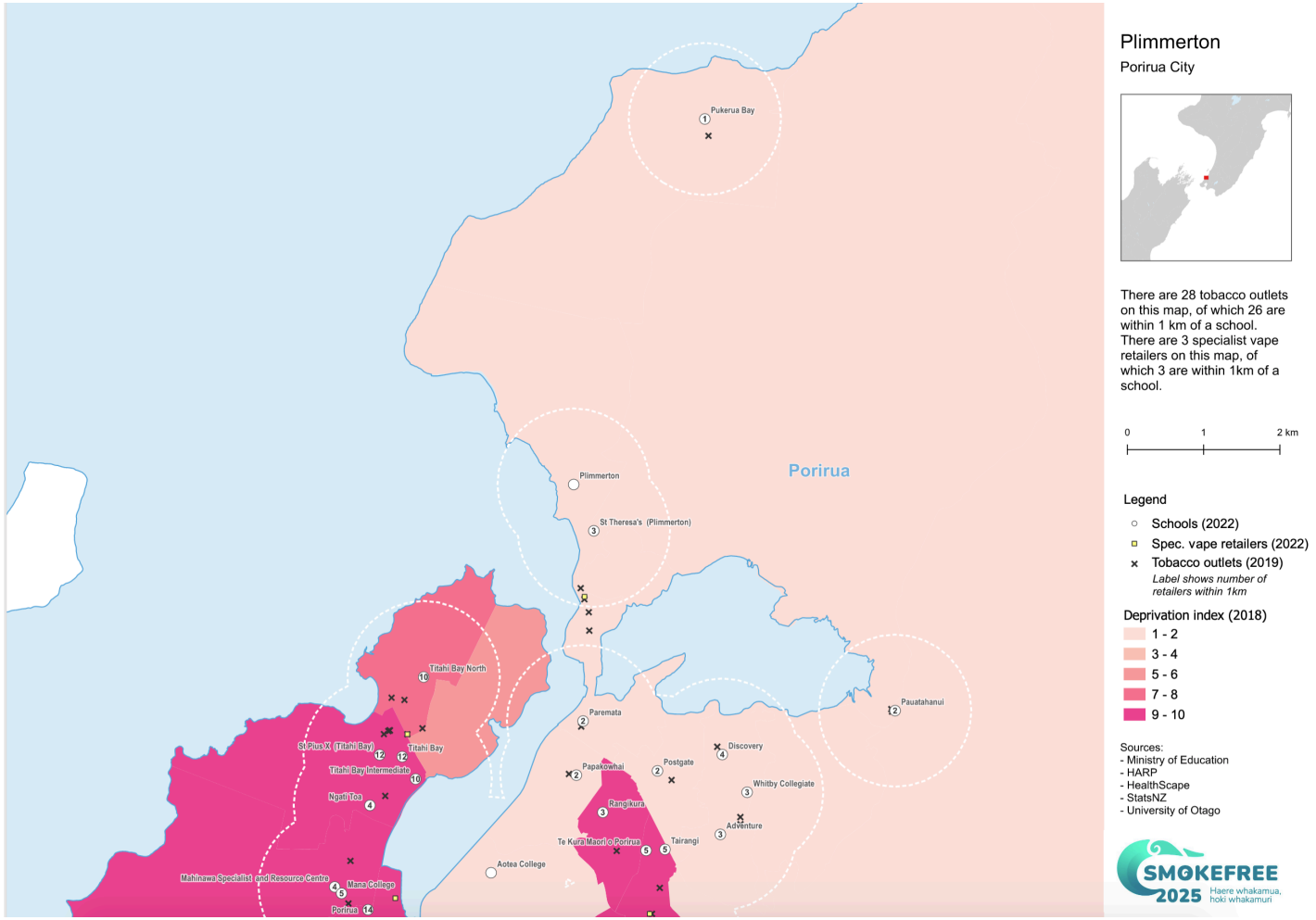
New Zealand society deals with a number of different illicit markets as per Table A2 below. To minimise the size of such markets and to reduce harm to health and wellbeing, governments typically use a variety of measures. These can include supply-side controls with enforcement, but also harm reduction measures (eg, free drug testing at concerts and needle exchange programmes). As such it seems strange that critics often argue for not progressing tobacco control because of potential illicit market implications. Instead, the appropriate response is to work on reducing demand for tobacco (as per this Bill) and to potentially strengthen and improve the targeting of smuggling control measures.

Table A2 Examples of other illicit markets and the range of government responses to minimise the size of these markets

Product	Types of governmental response to the illicit market
Illicit drugs and cannabis	Responses range widely around the world, but with most countries taking strong enforcement approaches (albeit varying by drug type). Some countries have been decriminalising some of these drugs as part of a harm reduction approach and have even been permitting legal sales (e.g., cannabis retailing in some US states). In New Zealand, Customs enforces border control efforts and Police focus on dealers (while taking a fairly minimal enforcement approach to possession of small amounts of cannabis). As well as supply side measures, the New Zealand Government also uses harm reduction measures (e.g., a national needle exchange programme and provision of drug testing at concerts).
Illegal firearms	Governments consistently take an enforcement approach. Sometimes there are amnesties to hand in illegal firearms and also gun-buy-back schemes (with these both having been used in New Zealand).
Sale of stolen goods	Governments take an enforcement approach and fairly consistently prosecute offenders. New Zealand Police conduct sting operations for stolen goods advertised online.[101]

Appendix 3: Example of STP and SVR outlet location map

The map shows the location of STR and STPs and schools in the Porirua and Plimmerton areas. The map also shows that many schools, particularly those within the more deprived areas, have ten or more STR and SVR retailers within one kilometre.



Appendix 4: Detailed suggestions for revisions to offence provisions

Our submission recommends that offence provisions generally should be rephrased as strict liability offences with defences, as outlined in the 'Offence Provisions' section above. Recasting the offences as 'strict liability' would mean removal of 'fault' elements (which would need to be proved by the enforcement agency), such as 'knowingly' or 'recklessly'. Strict liability is generally accompanied by defences such as 'without reasonable excuse' to be available to the person charged, but that the onus of proof for establishing such an excuse be on that person. A strict liability approach is that taken in general by the existing Act, and we are not clear why it has been changed in the new Bill. We recommend in general that the existing approach be continued with consequent changes to the Bill.

We recommend the following wording changes be adopted to give effect to strict liability and defence provisions, along with other recommendations for changes to offence-related provisions.

1 ***New sections 20J(6) and (7) (see clause 13)*****:** These say that 'a person whose approval (as a smoked tobacco retailers is suspended must not sell a smoked tobacco product during period of suspension' and that if a person does so, *knowingly or recklessly,* the person commits an offence liable to $400,000.

Comment: We disagree with the inclusion of *knowingly or recklessly* and recommend the same wording as for new section 20G. This states that a person who without reasonable excuse contravenes the duty not to sell commits an offence. This is a form of strict liability, along with a defence 'without reasonable excuse'.

2 ***New sections 20R and S (clause 13)*****:** The offences in 20R(3) and 20S(3) both concern failure to notify the Director-General that the person is a general retailer of vaping or distributor of smoked tobacco products. Both offences are specified as infringement offences, (see clause 47 amending current section 87 with fines of up to $5,000).

Comment We consider that both offences are serious ones and should not be regarded as infringement offences. Notification will be the only source of information that the DGH will have that a particular person is a general vaping retailer (as the provisions relating to specialist retailers do not apply). Similarly, there is no approval system relating to distributors of smoked tobacco products, unlike retailers. We consider that such offences should be ordinary strict liability offences and not be specified as 'infringement' (that is, clause 47 would require amendment); and that the penalty should be significantly greater, and at least $10,000.

3 ***Amendment to section 40 (see clause 19) amending 40 (prohibition of sale to under 18s.):*** As noted under "Introducing a Smokefree Generation policy", a drafting error has occurred here, in conjunction with commencement provisions, with the effect that the law would discontinue the existing ban on the sale of tobacco to people under 18. We assume that the error will be addressed so that the prohibition of sale to under 18s of regulated products continues until 2027; from which date the offence would only applies to notifiable products.

While it will be easy to rectify the mistake by a change to clause 2 (the commencement provisions), it would be clearer to draft this ban on sales on sales to under 18s in two different sets: as outlined above.

We note that the offence provisions in this section constitute strict liability, with more precise 'defence' provisions than the 'without reasonable excuse' wording which is generally used in the Bill. The amendment leaves unchanged sections 40(2) and (3) in the present Act. We consider that that is appropriate.

4 ***New section 40A:*** This is about the sale of STPs, to persons born on or after 1 January 2009. We do not agree with including the phrase 'knowingly or recklessly' as an element of the offence. The offence should be strict liability with a 'reasonable excuse' defence available to the person charged.

5 ***New section 40B:*** This is about *supply* (not sale) of STPs in a public place to persons born on or after 1 January 2009. This uses the 'knowingly or recklessly' wording. Again, this differs from the existing statutory provision (section 41, current Act) which provides for strict liability and defence. Further recommendations regarding this section are outlined under "Introducing a smokefree generation policy" (p27-29).

6 ***Clause 23 replaces existing section 44 with a new section 44****:* This relates to internet purchase information or warnings. If our provision on a ban on retailing of STPs via the internet is accepted (see "Reducing the number of Smoked Tobacco Product retailers"), this provision would only apply to notifiable products (vaping and smokeless tobacco).

We agree with this strict liability and defence formula, but suggest a significantly greater fine than $2000 would be appropriate, given the difficulty of enforcing this provision in relation to internet sales.

7 ***Clause 25 inserting new section 47 re vending machines*****:** We are happy with this strict liability and defence formula, but suggest a significantly greater fine than $2000 would be appropriate.

8 ***New section 57A (1) and (2):*** These create an offence for selling STPs that are not approved by Director-General. We do not agree that '*knowingly or recklessly*' should be included as elements of the offence. We recommend that a strict liability and defence formula be used. We endorse the level of fine, i.e., $600,000.

9 ***New section 57C(7) and (8):*** This establishes an offence if a person whose approval is suspended sells a STP. We do not agree with the '*knowingly or recklessly*' requirement and propose the strict liability and defence formula.

10 ***New section 57E (2):*** provides that a person who sells STPs with prohibited constituents commits an offence but only if done 'knowingly or recklessly'. We do not agree with the *'knowingly or recklessly'* requirement and recommend the strict liability and defence formula.

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